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Reregistration Eligibility Decision for DCNA (Dicloran)

June 14, 2006

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United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA-738-F-05-003
June 2006

Reregistration Eligibility Decision

DCNA (Dicloran)

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Reregistration Eligibility Decision (RED) Document for DCNA (Dicloran)

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Approved by: /s/

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Date: June 14, 2005

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
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
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
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.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
Φg/g	Micrograms Per Gram
Φg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure

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MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TCPSA	2,3,3-trichloroprop-2-ene sulfonic acid (nitrapyrin Metabolite)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (hereafter referred to as EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all tolerances in effect on the day before it was enacted. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process. FQPA also amended the FFDCA to require a safety finding in tolerance reassessment based on factors that include an assessment of cumulative effects of chemicals with a common mechanism of toxicity.

FQPA requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism of toxicity could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for DCNA and any other substances, and DCNA does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that DCNA shares a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/oppsrrd1/cumulative/.

This document presents EPA's revised human health and ecological risk assessments and its progress toward tolerance reassessment, and the reregistration eligibility decision for DCNA. The document consists of six sections: section I contains the regulatory framework for reregistration/tolerance reassessment; section II provides a profile of the use and usage of the chemical; section III gives an overview of the revised human health and environmental effects risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments, section IV presents the Agency's reregistration eligibility and

risk management decisions; section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and section VI provides information on how to access related documents. Finally, the Appendices list related and supporting documents and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available in the Public Docket under docket number EPA-HQ-2005-0265 located on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

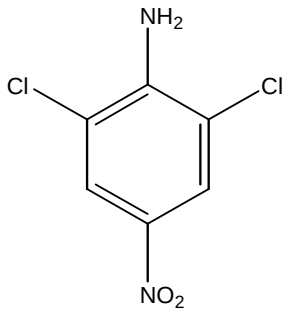
II. Chemical Overview

A. Regulatory History

DCNA was first registered for use in the United States in 1961. A Registration Standard for DCNA was completed in 1983, and Data Call-Ins (DCIs) were issued in 1983, 1994 and 1995. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data submitted to date, and presents the Agency's assessment of risks from all currently registered uses.

B. Chemical Identification

Figure A. Chemical structure of DCNA



Common Name:	DCNA (Dicloran)
Chemical Name:	2,6-dichloro-4-nitroaniline (IUPAC) 2,6-dichloro-4-nitrobenzenamine (CAS)
Chemical Class:	Substituted Aniline
Empirical Formula:	$C_6H_4Cl_2N_2O_2$
CAS Registry Number:	99-30-9
Case Number:	0113

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OPP Chemical Code: 031301

Molecular weight: 207

Vapor Pressure: 2.61×10^{-4} mm Hg at 25º C

Basic Manufacturer: Gowan Company

Technical DCNA is a yellow powder with a melting point range of 193.3-194.8ºC. DCNA is practically insoluble in water and other compounds with a water solubility of 31.0 mg/L at 25 ºC. DCNA is a member of the substituted aniline group of fungicides.

C. Use Profile

The following is information on the currently registered uses of DCNA, including an overview of use sites and application methods. A detailed table of the uses of DCNA eligible for reregistration is contained in Appendix A.

Type of Pesticide:	Fungicide
Summary of Use:	Preventative and curative fungal spore germination inhibitor
Food uses:	Currently registered food uses include apricots, beans (snap), carrots, celery, cherries, cucumber, endive (escarole), fennel, garlic, grapes, lettuce (head and leaf), nectarines, onions, peaches, plums, potatoes (white/Irish), prunes, rhubarb, shallots, sweet potatoes and tomatoes. Proposed new uses include peanuts, tomatoes (post-harvest), and carrots (pre-harvest). Also registered for use in greenhouses on cucumbers, lettuce, rhubarb, seed potatoes or transplants, and tomatoes. The major pre-harvest crop uses include celery, lettuce, snap beans, and grapes; the major post-harvest use is on sweet potatoes.
Formulation Type:	Liquid flowable, wettable powder (with and without water soluble bags), and dust
Manufacturer:	Gowan Company
Application Methods:	Aerial spray, airblast, groundboom, chemigation, hand application methods (handwands and backpack sprayers), dip tanks, and sprinkler irrigation

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Application Rates:	Current maximum application rates range from 0.0172 to 4.5 lb ai/acre. Sweet potato seed pieces may be treated at 2.8 lb ai/1,000 square feet of plantbed. The maximum yearly application rate for all crops is 4 lb ai/acre (except for potatoes at 7.5 lb ai/acre/year, and celery and fennel at 5 lb ai/acre/year). Current label requirements specify 12-hour restricted-entry intervals (REIs) and 1 to 14 day preharvest intervals (PHIs).
Application Timing:	Pre-plant, at plant, post-plant, and/or post-harvest
Use Classification:	General

D. Estimated Usage of Pesticide

Over 200,000 pounds of DCNA is applied annually throughout the United States. DCNA's primary uses are on celery, lettuce, and grapes. EPA's use data indicate that the percent of crop treated with DCNA is less than 2.5 percent for all crops except for celery (40 to 60 percent crop treated), lettuce (10 to 15 percent crop treated), grapes (5 to 15 percent crop treated, and snap beans (1 to 5 percent crop treated). DCNA is primarily used in California and the Pacific Northwest.

III. Summary of DCNA Risk Assessments

This section summarizes EPA's human health and ecological risk findings and conclusions for DCNA. This information is presented in greater detail in the following documents:

- *"Dicloran: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)"* (Goodlow, 05/11/06);
- *"Dicloran: Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document"* (Lloyd, 6/13/06);
- *"Dicloran (DCNA) Revised Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision (Phase 3)"* (Olinger, 3/23/06);
- *"Dicloran (DCNA) Residue Chemistry Considerations for the Reregistration Eligibility Decision (RED) Document. Summary of Analytical Chemistry and Residue Data"* (Olinger, 8/09/05)
- *"DCNA (Dicloran): Revised Tier I Drinking Water EDWC's for Use in the Human Health Risk Assessment"* (Sutton, 01/24/06); and
- *"Revised Ecological Risk Assessment in Support of the Reregistration Eligibility Decision on DCNA (Dicloran)"* (Sutton, 2/07/06).

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During the reregistration process, the technical registrant, Gowan Company, agreed to revise its manufacturing use and end-use products to limit the total amount of product that may be applied to a crop per year. This change was intended to decrease the ecological risks associated with DCNA. The ecological risk assessment was conducted using these limits on annual application amounts, and thus these limits are a required restriction on all DCNA products. The revised maximum yearly application limits are as follows:

- 4 pounds active ingredient per year (lb ai/acre/year) for all crops except for potatoes, celery, and fennel;
- 7.5 lb ai/acre/year for potatoes; and
- 5 lb ai/acre/year for celery and fennel.

The purpose of this section is to highlight the key features and findings of the risk assessments in order to help the reader better understand the risk management decisions reached by the Agency. While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket (docket number EPA-HQ-2005-0265) and may be accessed on the internet at http://www.regulations.gov.

A. Human Health Risk Assessment

1. Toxicity of DCNA

DCNA has low acute toxicity, but it is a potential skin sensitizer. The acute toxicity of DCNA is summarized below in Table 1.

Table 1. Acute Toxicity of DCNA

Guideline Number	Study Type	MRID Number	Results	Toxicity Category
870.1100	Acute Oral	00086879	LD_{50} = 1000 mg/kg	IV
870.1200	Acute Dermal	00086894	LD_{50} > 2000 mg/kg	III
870.1300	Acute Inhalation	Not Available	Not available	N/A
870.2400	Primary Eye Irritation	00086892	Mild ocular irritant	III
870.5200	Primary Skin Irritation	00086893	Not a dermal irritant	IV
870.2600	Dermal Sensitization	00082721	Potential dermal sensitizer	N/A

The toxicological database on DCNA is adequate, with the exception of a developmental neurotoxicity (DNT) study in rats and a 28-day inhalation toxicity study in rats. The target organs for DCNA include the liver, kidney, spleen and hematopoietic system, particularly red blood cells. DCNA does not appear to be a reproductive toxicant, with no reproductive effects observed in studies. The developmental toxicity study in rats showed increased incidences of

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supernumerary rudimentary ribs and also decreased fetal weights in the presence of maternal toxic dose.

The available data did not demonstrate neurotoxicity with subchronic dosing at doses lower than 25 mg/kg/day. However, neuropathology was seen in a long-term rat study. Also, neuropathology was seen in a chronic dog study at lower levels than the neuropathology seen in the long-term rat study.

A two-year combined chronic toxicity and carcinogenicity study in rats showed that DCNA caused reduced body weight, reduced body weight gain, and histopathologic lesions in the brain and spinal cord of both sexes, lesions in the optic nerve in females, and Leydig cell hyperplasia in the testes in males. The incidence of Leydig cell tumors was significantly increased in high-dose male rats compared with controls, and the incidence of endometrial adenocarcinoma was marginally increased in high-dose female rats. An 18-month mouse carcinogenicity study showed no treatment-related increase in tumor incidence. Based on these studies, EPA determined that DCNA should be classified as "Suggestive Evidence of Carcinogenic Potential" but concluded that no quantification of cancer risk is required.

A developmental rat study, a one-year dog study, and a 90-day oral dog study were the primary studies used for the human health assessment. In the studies reviewed, the dog is the most sensitive species to DCNA, with effects occurring at considerably lower doses than those noted for the rat or mouse.

For the acute dietary assessment, EPA used a rat developmental study (MRID 46447501) to assess risks for the population group of females 13-49 years of age. A developmental study is appropriate for assessing acute risks because developmental effects are presumed to occur as a result of a single dose at a critical time during gestation. In the risk assessment, EPA used the developmental no observed adverse effect level (NOAEL) of 50 mg/kg/day based on increased incidences of supernumerary rudimentary ribs and also decreased fetal weights at 100 mg/kg/day (the lowest observed adverse effect level [LOAEL]). EPA did not assess the acute dietary risks to other population subgroups because there were no other effects observed in oral toxicity studies with DCNA that are attributable to a single exposure.

For the chronic dietary assessment, EPA used a one-year chronic toxicity study in dogs (MRID 45610801). EPA used a NOAEL of 2.5 mg/kg/day based on clinical chemistry (increased alkaline phosphatase in both sexes and increased cholesterol in males), increased liver weights, hepatocyte hypertrophy, vacuolar alterations of the brain and spinal cord, prostate atrophy, degeneration of the seminiferous tubules, and hypospermia in the epididymides at the LOAEL of 25 mg/kg/day.

For the occupational risk assessment, EPA used a 21-day dermal toxicity study in rabbits (MRID 40555101) to estimate occupational risks from dermal exposure. EPA selected a NOAEL of 120 mg/kg/day based on increased adrenal weights in males at the LOAEL of 1200 mg/kg/day. This finding was corroborated by the histopathological changes observed in the adrenals at 150 mg/kg/day in the 90-day feeding study in rats (MRIDs 00029056 and 00082718).

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To estimate occupational risks from inhalation exposure, EPA used a 90-day oral toxicity study in dogs (MRID 000029056, 00026810), and assumed 100% absorption to account for route-to-route extrapolation, because there are no appropriate inhalation toxicity studies on DCNA. EPA selected a NOAEL of 2.5 mg/kg/day based on changes in hematological (decreased hemoglobin and hematocrit at 4, 8, and 14 weeks) and clinical biochemistry parameters, reduced body weight gain, increased liver, spleen and kidney weights, and histopathological changes in the liver at the LOAEL of 75 mg/kg/day.

FQPA Safety Factor

FQPA directs EPA, in setting pesticide tolerances, to use an additional tenfold margin of safety to protect infants and children, taking into account the potential for pre- and post-natal toxicity and the completeness of the toxicology and exposure databases. The statute authorizes EPA to modify this tenfold FQPA safety factor only if reliable data demonstrate that the resulting level of exposure will be safe for infants and children.

The toxicity database for DCNA includes acceptable developmental and reproductive toxicity studies, and these studies showed no increase in susceptibility in fetuses and pups with *in utero* and post-natal exposure. However, EPA has determined that the FQPA safety factor must be retained to account for database uncertainties.

DCNA appears to elicit neuropathology (vacuolation in the brain) at doses of 25-75 mg/kg following exposures greater than 90 days. The neuropathological effects were greater in four-week-old rats than seven-week old rats, indicating that age could be an important variable in this neurotoxicity. Therefore, a developmental neurotoxicity (DNT) study is necessary to fully characterize potential fetal neurotoxicity and neuropathology. Since the DCNA database does not include a DNT study, an FQPA database uncertainty factor must be retained for scenarios in which exposure to children or pregnant women is expected. Furthermore, a DNT study is required for DCNA.

The size of the FQPA database uncertainty factor is based on an analysis of DNT studies previously submitted to the Agency which suggests that NOAELs from a DNT study could be lower than the lowest dose tested in the studies currently used in the risk assessment. For DCNA, a 10x FQPA database uncertainty factor is retained for both the acute and chronic dietary risk assessments because it is possible that the DNT could yield a NOAEL of up to ten times lower than the ones currently used for the risk assessment.

The toxicological endpoints and uncertainty factors used in the human health risk assessment for DCNA are listed below, in Table 2.

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Table 2. Summary of Doses, Toxicological Endpoints, and Uncertainty Factors for DCNA

Exposure Scenario	Dose and Uncertainty Factor	Study and Toxicological Effects
Acute Dietary (females 13-49)	Developmental NOAEL=50 mg/kg/day UF = 1000 (10x interspecies extrapolation, 10x intraspecies variation, and 10x FQPA Safety Factor) aPAD = NOAEL ÷ UF aPAD = 0.05 mg/kg/day	Developmental toxicity study in rats (MRID 46447501) Developmental LOAEL = 100 mg/kg/day based on increased incidences of supernumerary rudimentary ribs and decreased fetal weights
Acute Dietary (general population including infants and children)	A dose and endpoint were not selected for this population group because there were no effects observed in oral toxicology studies, including maternal toxicity in the developmental toxicity studies in rats and rabbits, which are attributable to a single exposure.	
Chronic Dietary (All populations)	NOAEL = 2.5 mg/kg/day UF = 1000 (10x interspecies extrapolation, 10x intraspecies variation, and 10x FQPA Safety Factor) cPAD = NOAEL ÷ UF cPAD = 0.0025 mg/kg/day	One-year chronic toxicity study in dogs (MRID 45610801) LOAEL = 25 mg/kg/day based on clinical chemistry (increased alkaline phosphatase in both sexes and increased cholesterol in males), increased liver weights, hepatocyte hypertrophy, vacuolar alterations of the brain and spinal cord, prostate atrophy, degeneration of the seminiferous tubules, and hypospermia in the epididymides
Short- (1-30 days) and Intermediate-Term (1-6 months) Occupational Dermal	NOAEL = 120 mg/kg/day UF = 100 (10x interspecies extrapolation and 10x intraspecies variation) Occupational level of concern (LOC) = MOE of 100	21-day dermal toxicity study in rabbits (MRID 40555101) LOAEL = 1200 mg/kg/day based on increased adrenal weights in males
Short- (1-30 days) and Intermediate-Term (1-6 months) Occupational Inhalation	Oral NOAEL = 2.5 mg/kg/day (Inhalation absorption rate assumed to be 100%) Occupational LOC = MOE of 100	90-Day feeding study in dogs (MRIDs 00029056, 00026810) LOAEL = 75 mg/kg/day based on hematological (decreased hemoglobin and hematocrit at 4, 8, and 14 weeks) and clinical biochemistry parameters, reduced body weight gain, increased liver, spleen and kidney weights and histopathological changes in the liver
Cancer	Classified as "Suggestive Evidence of Carcinogenic Potential," but no quantification of cancer risk is required.	

2. Residue Information

EPA has concluded that the parent compound should be included in the tolerance expression for enforcement purposes since residues of the parent are sufficient to include pesticidal misuse.

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For the risk assessments, EPA included 2,6-dichloro-4-hydroxyaniline (DCHA) and a group of metabolites designated as Unknown 1 in the residue profile. Unknown 1 was found to form only in the metabolism study on potatoes and adjustment factors were established to include DCHA and Unknown 1 in the risk assessment for various crops. For more information on the adjustment factors and how they apply to the risk assessment, please see *"Dicloran: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED),"* (T. Goodlow, 5/11/06).

3. Dietary (Food + Water) Exposure and Risk

EPA conducted acute and chronic dietary exposure assessments for DCNA using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998, as well as monitoring data from USDA's Pesticide Data Program (PDP), and processing/cooking factors, where appropriate.

(a) Acute and Chronic Dietary Risk from Food

The dietary assessment for DCNA considers residues from both DCNA and DCHA for all crops except potatoes. For potatoes, it includes residues of DCNA, DCHA, and Unknown 1. EPA applied the toxicity adjustment factors to account for residues of the metabolites of concern. Exposure estimates are reported in milligrams per kilogram of body weight per day, and risk is expressed as a percent of the acute Population Adjusted Dose (aPAD) or chronic Population Adjusted Dose (cPAD). A risk estimate that is less than 100% of the PAD does not exceed EPA's level of concern.

EPA conducted refined (Tier II and III) acute and chronic dietary assessments using USDA Pesticide Data Program (PDP) monitoring data for all commodities except rhubarb, assuming non-detectable residues were at the limit of detection. EPA assumed tolerance-level residues for rhubarb because no PDP data are available for rhubarb. As conservative assumptions, the Agency assumed 100 percent crop treated and limit of quantitation residues in all commodities.

At the 99.9th percentile of exposure, the estimated acute exposure for food was 9.9% of the aPAD for females aged 13-49, which is below the Agency's level of concern. For chronic risks, the population subgroup with the greatest exposure was children (1-2 years old) at 13% of the cPAD, which is below Agency's level of concern. A summary of the acute and chronic dietary (food only) risk estimates is presented in Table 3.

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Table 3. Dietary (Food Only) Exposure and Risk

Population Subgroup	Exposure, mg/kg/day	% PAD
Acute Dietary Estimates (99.9th Percentile)		
Females 13-49 years	0.0049	9.9
Chronic Dietary Estimates		
U.S. Population	0.00015	6.0
Children 1-2 yrs	0.00032	13

(b) Acute and Chronic Dietary Exposure and Risk from Drinking Water

The Agency calculated estimated drinking water concentrations (EDWCs) for surface water using the FQPA Index Reservoir Screening Tool (FIRST), Version 1.0. EPA used the SCI-GROW model, Version 2.3, to calculate ground water EDWCs. Both the surface water and ground water EDWC's are based on DCNA applied in a single aerial application to apricots at the rate of 4.0 lb ai/acre. The 4.0 lb ai/acre rate is the highest single application rate except for a Section 24(c) Special Local Need (SLN) label for potatoes that allows a maximum rate of 4.5 lb ai/acre. The SLN potato use is a minor use for DCNA and would generate lower EDWCs than aerial application to apricots because potatoes are treated with a directed spray application. The models are not site-dependent, and therefore the EDWCs determined for apricots are applicable to other crops receiving 4 lb ai/acre by aerial application.

The environmental fate database showed that there are no major degradates of concern for DCNA found in water. Thus, the surface and ground water assessment includes the parent compound only. The surface and ground water EDWCs for DCNA are presented in Table 4, below.

Table 4. Surface and Ground Water EDWCs for DCNA

	Acute EDWC	Chronic EDWC
Surface Water	172.8 ppb	1.8 ppb
Ground Water	1.3 ppb	1.3 ppb

(c) Acute and Chronic Dietary Exposure and Risk from Food plus Drinking Water

EPA conducted an acute and chronic aggregate dietary assessment using DEEM-FCID™. Food exposures and EDWCs from modeled values for surface water sources of drinking water were included. Surface water EDWCs were used rather than ground water EDWCs because modeling results predicted that surface water residues would be highest.

At the 99.9th percentile of exposure, the estimated food and water exposure for females 13-49 years old was 52% of the aPAD, which is below the Agency's level of concern. For

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chronic exposures, the most highly-exposed subgroup was children 1-2 years old, with exposures accounting for 15% of the cPAD, which is below the Agency's level of concern. A summary of the acute and chronic dietary (food plus drinking water) risk estimates is presented in Table 5.

Table 5. Dietary (Food + Drinking Water) Exposure and Risk

Population Subgroup	Exposure, mg/kg/day	% PAD
Acute Dietary Estimates (99.9th Percentile)		
Females 13-49 years	0.026	52
Chronic Dietary Estimates		
U.S. Population	0.00019	7.5
Children 1-2 yrs	0.00038	15

4. Residential Exposure and Risk

EPA did not conduct a residential assessment because there are no residential uses of DCNA.

5. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(iii)) require that "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. There are no residential uses of DCNA, nor other non-occupational sources of exposure. Therefore, when addressing aggregate exposures, the Agency considered only the aggregate dietary pathways of food and drinking water.

As noted above, acute and chronic aggregate exposure estimates for food and drinking water are below EPA's level of concern for all population subgroups. At the 99.9th percentile of exposure, the estimated food and water exposure for females 13-49 years old accounted for 52% of the aPAD. For chronic exposures, the most highly-exposed subgroup was children 1-2 years old, with exposures accounting for 15% of the cPAD.

6. Occupational Risk

(For a complete discussion, see Section 2.0 of the Revised DCNA Occupational and Residential Exposure HED Risk Assessment for Reregistration Eligibility Document (RED) by M. Lloyd dated 6/13/06).

Non-cancer risk estimates are expressed as a margin of exposure (MOE) which is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern which reflects the dose

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selected for risk assessment and uncertainty factors (UFs) applied to that dose. The standard UF is 100x which includes 10x for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10x for intraspecies variation (to account for differences between humans). Additional uncertainty or safety factors may also be applied. In the case of DCNA, EPA's level of concern for occupational exposures is an MOE of 100 which includes 10x for interspecies extrapolation and 10x for intraspecies variation.

Most occupational exposures are expected to occur in short-term periods (up to 30 days), but some intermediate-term exposures are anticipated in some handler exposure scenarios, particularly those involving applications by commercial applicators to large-acreage crops. Chronic exposures are those that would result from use of a pesticide for more than several months a year.

For DCNA, the Agency determined that pesticide handlers and applicators are likely to be exposed in short- (one day to one month) and intermediate-term (one to six month) durations. Chronic exposures (longer than six months) are not expected because DCNA would be used for controlling disease outbreaks only during the growing season.

EPA assessed the occupational handler scenarios using the short- and intermediate-term endpoints for dermal and inhalation exposures. The short- and intermediate-term dermal endpoint is a NOAEL of 120 mg/kg/day, from a 21-day dermal study in rabbits with a LOAEL of 1200 mg/kg/day based on increased adrenal weights in males (MRID 40555101). The short- and intermediate-term inhalation endpoint is a NOAEL of 2.5 mg/kg/day from a 90-day oral dog study with a LOAEL of 75 mg/kg/day based on hematological changes (MRIDs 00029056, 00026810). The dermal and inhalation endpoints are based on different toxicological effects on different organs, and therefore the Agency did not calculate combined dermal-inhalation MOEs.

(a) Occupational Handler Summary

Based on the labels and registered use patterns, EPA has identified six major handler exposure scenarios for DCNA.

1) Mixing/Loading wettable powders, dusts or liquids
2) Applying via aerial, groundboom, airblast, turfgun or high-pressure handwand application methods
3) Mixing/Loading/Applying wettable powders with a low-pressure (LP) handwand, backpack sprayer or turfgun
4) Mixing/Loading/Applying liquids with a LP handwand, backpack sprayer or turfgun
5) Mixing/Loading/Applying dusts with a handheld power duster
6) Flagging for aerial application liquids or dusts

No chemical-specific handler exposure data were submitted on DCNA, so short-term and intermediate-term dermal and inhalation exposures for handlers were developed using the Pesticide Handler Exposure Database (PHED) Version 1.1. Furthermore, for this risk assessment, the Agency used standard values for daily acres treated in agriculture in order to develop daily exposure estimates.

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The calculations of short- and intermediate-term dermal and inhalation risks to handlers indicate that most DCNA occupational handler risks are below the Agency's level of concern (i.e., MOEs are greater than 100) at some level of personal protective equipment (PPE) and/or engineering controls. Tables 6 and 7, below, present the short- and intermediate-term dermal and inhalation MOEs for all agricultural handler scenarios.

Table 6. DCNA Short/Intermediate Term Dermal MOEs for Agricultural Handlers

Exposure Scenario	Max. Rate (lb ai/acre)	Acres per Day	Level of Personal Protective Equipment			Engineering Controls[4]
			Baseline[1]	Single Layer[2]	Double Layer[3]	
Mixing and loading dust to support aerial application[5]	4.0	350	2	35	46	N/A
Mixing and loading dust to support ground application	4.0	40	14	310	400	N/A
Mixing and loading wettable powder to support aerial application or chemigation	4.5	350	1	31	41	≥ 610
Mixing and loading wettable powder to support groundboom application	120[6]	3	6	140	180	>1000
	4.5	80	6	140	180	>1000
Mixing and loading wettable powder to support airblast application	4.0	40	14	310	400	>1000
Mixing and loading wettable powder to support high-pressure handwand application	2.5	10	94	>1000	>1000	>1000
Mixing and loading liquid to support aerial application or chemigation	4.0	350	2	260	350	700
Mixing and loading liquid to support groundboom application	4.0	80	9	>1000	>1000	>1000
Mixing and loading liquid to support airblast application	4.0	40	18	>1000	>1000	>1000
Applying aerially	4.5	350	N/A - It was assumed that only engineering controls are used			>1000
Applying with groundboom equipment	4.5	80	>1000	>1000	>1000	>1000
	120[6]	3	>1000	>1000	>1000	>1000
Applying with airblast equipment	4.0	40	150	220	240	>1000
Applying with a high-pressure handwand	2.5	10	260	>1000	>1000	No data
Mixing, loading, and applying wettable powder with a low-pressure handwand	2.5	0.4	No Data	≥490	≥680	No Data
Mixing, loading, and applying liquid with a low-pressure handwand	2.5	0.4	No data			

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Exposure Scenario	Max. Rate (lb ai/acre)	Acres per Day	Level of Personal Protective Equipment			Engineering Controls[4]
			Baseline[1]	Single Layer[2]	Double Layer[3]	
Mixing, loading, and applying liquids with a backpack sprayer	2.5	0.4	84	>1000	>1000	No data
Flagging activities to support aerial application	4.5	350	480	No Data	530	>1000

[1] Baseline PPE includes typical work clothing (i.e., a long-sleeved shirt, long pants, shoes, socks, and no respiratory protection). It does not include chemical-resistant gloves.
[2] Single layer PPE includes chemical-resistant gloves in addition to baseline clothing.
[3] Double layer PPE adds coveralls to single layer PPE.
[4] Engineering controls includes enclosed tractor cab, enclosed cockpit, water soluble bags, or closed loading systems.
[5] PHED data for mixing and loading wettable powders were used to calculate dermal exposure for mixing and loading dust.
[6] Sweet potato plantbeds may be sprayed with DCNA at a maximum rate of 2.8 lb ai per 1,000 square feet of plant bed. This rate is equivalent to 120 lb ai/acre, with an assumption of a maximum of 3 acres treated per day.

Table 7. DCNA Short/Intermediate Term Inhalation MOEs for Agricultural Handlers

Exposure Scenario	Max. Rate (lb ai/acre)	Acres per Day	Level of Personal Protective Equipment			Engineering Controls[4]
			Baseline[1]	PF5[2]	PF10[3]	
Mixing and loading dust to support aerial application[5]	4.0	350	3	15	29	N/A
Mixing and loading dust to support ground application	4.0	40	25	130	250	N/A
Mixing and loading wettable powder to support aerial application or chemigation	4.5	350	3	13	26	≥ 460
Mixing and loading wettable powder to support groundboom application	120[6]	3	11	57	110	>1000
	4.5	80	11	57	110	>1000
Mixing and loading wettable powder to support airblast application	4.0	40	25	130	250	>1000
Mixing and loading wettable powder to support high-pressure handwand application	2.5	10	160	>1000	>1000	>1000
Mixing and loading liquid to support aerial application or chemigation	4.0	350	100	520	1000	>1000
Mixing and loading liquid to support groundboom application	4.5	80	410	>1000	>1000	>1000
Mixing and loading liquid to support airblast application	4	40	910	>1000	>1000	>1000
Applying aerially	4.5	350	N/A - It was assumed that only engineering controls are used			>1000
Applying with groundboom equipment	120[6]	3	≥660	>1000	>1000	>1000
	4.5	80	≥660	>1000	>1000	>1000

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Exposure Scenario	Max. Rate (lb ai/acre)	Acres per Day	Level of Personal Protective Equipment			Engineering Controls[4]
			Baseline[1]	PF5[2]	PF10[3]	
Applying with airblast equipment	4.0	40	240	>1000	>1000	>1000
Applying with a high-pressure handwand	2.5	10	>1000	>1000	>1000	ND
Mixing, loading, and applying wettable powder with a low-pressure handwand	2.5	0.4	160	>1000	>1000	No Data
Mixing, loading, and applying liquid with a low-pressure handwand	2.5	0.4	No Data			
Mixing, loading, and applying liquids with a backpack sprayer	2.5	0.4	>1000	>1000	>1000	No Data
Flagging activities to support aerial application	4.5	350	320	>1000	>1000	>1000

[1] Baseline PPE includes typical work clothing and no respiratory protection.
[2] A PF5 respirator is a filtering facepiece respirator (i.e., a dust mask) with a protection factor of 5.
[3] A PF10 respirator is a half-face cartridge respirator with a protection facor of 10.
[4] Engineering controls includes enclosed tractor cab, enclosed cockpit, or water soluble bags.
[5] PHED data for mixing and loading wettable powders were used to calculate inhalation exposure for mixing and loading dust.
[6] Sweet potato plantbeds may be sprayed with DCNA at a maximum rate of 2.8 lb ai per 1,000 square feet of plant bed. This rate is equivalent to 120 lb ai/acre, with an assumption of a maximum of 3 acres treated per day.

(b) Post-Application Occupational Risk

EPA considered exposure to DCNA to workers entering treated fields and orchards in its post-application occupational risk assessment. Restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before workers can safely reenter (i.e., when MOEs would be greater than or equal to 100). Potential exposure scenarios include key tasks such as harvesting, thinning, and pruning, as well as secondary tasks, such as scouting, irrigating, and hand weeding. The use of PPE or other types of equipment to reduce exposures for post-application workers is not considered a viable alternative to mitigate post-application risks.

For the post-application exposure assessment, EPA used a dislodgeable foliar residue (DFR) study conducted on snap beans with groundboom application of Botran 75W, a 75% wettable powder formulation. The Agency extrapolated the available DFR data to other crops, and adjusted the data for differences in application rate using a simple proportional approach. Risks were calculated using generic transfer coefficients that represent many different types of cultural practices which were associated with each crop group.

The post-application risks for DCNA are summarized in Table 8, below. Within each crop group, differing transfer coefficients were used to represent different types of cultural practices which were applicable to each crop group. Most of the MOEs for DCNA are below the Agency's level of concern (i.e., are greater than 100) at the currently labeled REI of 12 hours for short- and intermediate-term risks. For some crops, however, longer REIs or decreased application rates are required to achieve MOEs greater than or equal to 100.

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Table 8. – DCNA Post-application Short- and Intermediate-Term Risks

Crop Group	Application Rate (lb a.i/acre)	MOE for the Highest Post-Application Exposure Activity	Days until MOE > 100
Field/Row Crops, Low/Medium	3	64	13
Cut Flowers	0.75 1	130 94	0 (12 hours) 2
Ornamentals, Potted Plants	0.75	1590	0 (12 hours)
Vegetable, Cucurbit	1	190	0 (12 hours)
Vegetable, Fruiting	0.75	640	0 (12 hours)
Tree, Fruit, Deciduous	4	40	30
Tree, Fruit, Evergreen	2	80	7
Vegetable, Leafy, Greenhouse	2	95	3
Vegetable, Leafy, Outdoors (celery, lettuce) (endive)	4 2	80[1] 95	7 2
Vegetable, Root (onions, garlic shallots) (potatoes) (sweet potatoes)	4 4.5 2.8	80 70 570	7 10 0 (12 hours)
Vine/Trellis grapes	3.5	14	55

[1]When DCNA is applied to celery at the maximum application rate of 4 lb ai/acre, it is applied as a direct spray to the base of the plant and adjacent soil. When DCNA is applied to lettuce at the maximum application rate of 4 lb ai/acre, it is applied as a basal soil drench immediately after thinning. The MOE of 80 corresponds to the highest exposure activity expected to follow these types of applications to celery and lettuce (thinning and weeding).

7. Human Incident Data

EPA consulted the following databases for poisoning incident data on DCNA: OPP Incident Data System (IDS), Poison Control Centers, California Department of Pesticide Regulation, National Pesticide Information Center (NPIC), and the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR). There were no poisoning reports due to DCNA exposure in the OPP IDS, California Department of Pesticide Regulation (1982-2002), NPIC (1984-1991), and NIOSH SENSOR (1998-2002) databases. Additionally, there were no incidents of poisoning or other human health effects related to DCNA found in scientific literature.

A total of seven poisoning cases were reported in the Poison Control Center records from 1993 through 2001. Two involved children under the age of six, one involved an individual who was exposed in an occupational setting, and the remaining four involved adults exposed in non-occupational settings. Only one of these seven cases resulted in a medical symptoms, which

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were characterized as minor dermal symptoms. Based on the small number of incidents and the lack of severity of these incidents, the Agency has concluded that there is no evidence of significant harm.

B. Environmental Risk Assessment

1. Environmental Exposure

(a) Environmental Fate and Transport

DNCA has low volatility and is expected to be persistent and have low mobility in soil, although mobility will be increased in coarser soils. Degradation of DCNA is faster under anaerobic soil conditions than under aerobic soil conditions. In aerobic mineral soils, the half-life ranged from six to eighteen months. In anaerobic sandy soils, the half-life ranged from twenty-four to thirty-eight days.

DCNA has a moderate potential to bio-accumulate in fish tissue based on a bioconcentration study which indicated a 136X bioconcentration factor (BCF) in whole fish tissue. However, the bioaccumulated residues were almost completely eliminated from fish tissues (86-98%) during a 7-14 day depuration period.

(b) Aquatic Organism Exposure

For exposure to fish and aquatic invertebrates, EPA considers surface water only, since most aquatic organisms are not found in groundwater. The Agency used PRZM (version 3.12 beta)/EXAMS (version 2.98.04) to estimate exposure to aquatic animals. Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factors represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the Estimated Environmental Concentration (EEC) values used to assess exposure to aquatic animals are not the same as the values used to assess human dietary exposure from drinking water sources.

Several crop scenarios were assessed in the ecological risk assessment, including California (iceberg) lettuce, California grapes (Northern and Southern), Idaho potatoes, California onions, Oregon vegetables (snap beans), and North Carolina peanuts. The modeled potato use scenario reflects the maximum annual application rate allowed on the labels. This use rate is associated with the Special Local Need (SLN; Section 24C) uses allowed only in Idaho, California, Oregon and Washington. While the *single* maximum rate for potatoes (4.5 lb ai/acre) is higher than for any other crop, preliminary modeling indicated that the use of the maximum *annual* rate (7.5 lb ai/acre, applied in five applications of 1.5 lb ai/acre) yielded higher acute and chronic EECs than the single maximum rate.

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The EEC values used to assess exposure to aquatic animals are provided in Table 9, below.

Table 9. Surface water EECs for ecological exposure based on DCNA use on multiple crops

Crop	Acute (ppb)	1-in-10 Year 21-day Concentration (ppb)	1-in -10 Year 60-day Concentration (ppb)
CA lettuce	42.3	22.9	11.0
CA grapes	9.8	3.4	1.6
ID potatoes	11.2	5.4	3.1
CA onions	0.2	0.1	0.05
OR snapbeans	28.9	19.7	12.9
NC peanuts	34.1	10.9	5.3

(c) Terrestrial Organism Exposure

The Agency assessed exposure to terrestrial organisms by first predicting the amount of DCNA residues found on animal food items and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. Current labels allow a single application of 4.0 lb ai/acre for various crops, and five applications per year for potatoes at a rate of 1.5 lbs ai/acre, for an annual maximum application rate of 7.5 lbs ai/acre/year.

Terrestrial exposure estimates for avian and mammalian risk assessments were derived using the TREX model (Version 1.1), which calculates the decay of a chemical applied to surfaces of food items as single or multiple applications. A complete list of the EEC values used to assess exposure to terrestrial animals can be found in the ecological risk assessment.

2. Environmental Effects (Hazard)

(a) Toxicity to Aquatic Organisms

i. Freshwater and Estuarine/Marine Fish

DCNA (technical grade) is classified as highly toxic to freshwater fish in acute toxicity tests with rainbow trout and bluegill sunfish (the median lethan concentration (LC_{50}) values are 0.9 and 1.1 mg ai/L, respectively). An acute toxicity test with the formulated product, Botran 50W, resulted in 96-hr LC_{50} values of 4.1 and 7.0 mg/L (parts per million (ppm)) for bluegill and rainbow trout, respectively. This DCNA formulation is classified as moderately toxic to freshwater fish. To assess chronic risk, EPA used a non-guideline study in which growth of juvenile fish exposed to DCNA was evaluated (NOAEC = 0.049 mg ai/L).

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DCNA is moderately to highly toxic to freshwater fish based on acute exposures in rainbow trout (*Oncorhynchus mykiss*) and bluegill sunfish (*Lepomis macrochirus*). The results of these studies are provided in Table 10, below. Guideline studies are not available to assess chronic toxicity of DCNA to freshwater fish, and acute and chronic toxicity to estuarine/marine fish.

Table 10. Freshwater Fish Toxicity Estimates using DCNA

Species	Acute Toxicity		Chronic Toxicity	
	96-hr LC_{50} (mg/L)	**Acute Toxicity Category**	**NOAEC / LOAEC[1] (mg/L)**	**Affected Endpoints**
Rainbow Trout *Oncorhynchus mykiss* (TGAI)	0.9	Highly Toxic (MRID 00096064)	0.049 / 0.155	Juvenile Growth (MRID 46657102)
Bluegill Sunfish *Lepomis macrochirus* (Botran 50W)	4.1	Moderately Toxic (MRID 00096062)	--	--

[1]No observed adverse effect concentration / lowest observed adverse effect concentration

ii. Freshwater and Estuarine/Marine Invertebrates

DNCA is classified as moderately toxic to freshwater invertebrates under acute exposure based on a study with *Daphnia magna* (the effective concentration (EC_{50}) is 2.1 mg/L). To assess chronic toxicity, EPA used a 21-day toxicity study on *Daphnia magna*, which showed a NOAEC of 0.03 mg ai/L. A supplemental freshwater 28-day sediment dwelling toxicity study (on *Chironomus riparius*) showed no significant effects from DCNA. The study results are provided in Table 11.

Table 11. Freshwater Invertebrate Toxicity Estimates using DCNA

Species	Acute Toxicity		Chronic Toxicity	
	48-hour EC_{50}[1] (mg ai/L)	**Acute Toxicity**	**NOAEC / LOAEC[2] (mg/L)**	**Affected Endpoints**
Water flea *(Daphnia magna)*	2.1 (NOEC= 1.0)	Moderately Toxic (MRID 40583102)	0.03 / 0.10	Reproduction (offspring per parent) (MRID 46657103)
Midge *(Chironomus riparius)*	--	--	2.4 / >2.4 (water) 1.2 / >1.2 (sediment)	No Significant Effects (MRID 46657104)

[1] Effective concentration
[2] No observed adverse effect concentration / lowest observed adverse effect concentration

iii. Aquatic Plants

In a 72-hour green algae (*Scenedesmus subspicatus*) toxicity study, DCNA produced significant effects on algal cell density, growth rate and biomass at all tested concentrations. As

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a result, the NOEC and LOEC were <0.135 mg/L and 0.135 mg/L (the lowest tested concentration). The lowest EC50 was was 0.12 mg/L for effects on biomass.

b. Toxicity to Terrestrial Organisms

i. Birds

In acute avian toxicity tests, DCNA is classified as slightly toxic to bobwhite quail (LC_{50} = 900 mg/kg bw) and practically non-toxic to mallard ducks. In a sub-acute study with bobwhite quail, the LC_{50} was 1219 mg/L. To assess chronic toxicity, EPA used a bobwhite quail reproduction study with a NOAEC of 387 mg/kg-feed. The results of these studies are provided in Table 12, below.

Table 12. Avian Toxicity Estimates using DCNA

Species	Acute Toxicity				Chronic Toxicity	
	LC_{50}[1] (mg/kg-bw)	**Acute Oral Toxicity (MRID)**	**8-Day LC_{50} (mg/L)**	**Subacute Dietary Toxicity (MRID)**	**NOAEC / LOAEC[2] (mg/kg)**	**Affected Endpoints**
Northern bobwhite quail *(Colinus virginianus)*	900	Slightly Toxic (MRID 43755101)	1219	Slightly Toxic (MRID 43115501)	387 / 967	Growth and Reproduction (MRID 46218900)

[1] Median lethal concentration
[2] No observed adverse effect concentration / lowest observed adverse effect concentration

ii. Mammals

DCNA is classified as practically non-toxic to mammals on an acute oral basis (median lethal dose (LD_{50}) is 3400 mg/kg-bw). To assess chronic toxicity, EPA used a two-generation reproduction study in rats. A parental and reproductive NOAEC of 250 ppm was observed, with decreased pup weights observed at the LOAEC of 1250 mg/L. See Table 13, below, for a summary of the data.

Table 13. Mammalian Toxicity Endpoints for DCNA

Species	Acute Toxicity		Chronic Toxicity	
	LC_{50}[1] (mg/kg-bw)	**Acute Oral Toxicity**	**NOAEC / LOAEC[2] (mg/L)**	**Affected Endpoints**
Rat *(Rattus norvegicus)*	3400 (48.8% formulation)	Practically Non-Toxic (MRID 000242341)	250 / 1250 (MRIDs 44233803, 44474101)	Decreased Pup Weights

[1] Median lethal concentration
[2] No observed adverse effect concentration / lowest observed adverse effect concentration

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iii. Non-Target Insects

There is a potential for honey bee exposure due to DCNA foliar applications. A honey bee acute toxicity study showed that DCNA is practically non-toxic to the honey bees with an LD_{50} greater than 181 micrograms per bee.

iv. Non-target Terrestrial Plants

No acute or chronic non-target terrestrial or semi-aquatic plant data were presented. Therefore, risks to non-target terrestrial plants cannot be assessed.

3. Ecological Risk Estimation (RQs)

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to EECs which are based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of DCNA products, the Agency calculates a risk quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). These RQ values are then compared to the Agency's levels of concern (LOCs), which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern for that category. These risks of concern may be addressed by further refinements to the risk assessment or mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills). The Agency's levels of concern are provided in Table 14.

Table 14. EPA's Levels of Concern and Associated Risk Presumptions

Risk Presumption	LOC for Terrestrial Animals	LOC for Aquatic Animals	LOC for Plants
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Endangered Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	N/A

a. Risk to Aquatic Organisms

i. Fish and Aquatic Invertebrates

No acute or chronic RQs exceeded the LOCs for freshwater fish or invertebrates, with the exception of the use of DCNA on celery (modeled with lettuce scenario) in which the RQ

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exceeded the listed-species acute risk LOC for freshwater fish at the peak predicted EEC. No acute or chronic toxicity data are currently available for estuarine/marine fish or invertebrates, and therefore risks to estuarine/marine species could not be assessed. However, no risks would be expected for estuarine animals based on the low risks to freshwater animals.

ii. Aquatic Plants

The RQs for non-vascular plants did not exceed the acute risk LOCs. No toxicity data are available for aquatic vascular plants, and therefore risks to these species cannot be assessed. However, based on the lack of adverse effects to aquatic non-vascular plants, the Agency does not expect adverse effects in aquatic vascular plants from DCNA exposure.

b. Risk to Non-target Terrestrial Organisms

i. Birds

In this screening-level assessment, avian RQs were calculated based on maximum residues on forage items, using a bobwhite quail LD_{50} of 900 mg/kg-bw from an acute oral study and a NOAEC of 387 ppm from an avian reproduction study. At the single application rate of 4 lbs ai/A, the highest acute RQ is for small birds feeding on short grass (RQ = 1.72). Following multiple applications of DCNA (5 applications of 1.5 lbs ai/A to potatoes), the acute risk LOC (0.5) is exceeded for all food types (the highest RQ is 2.49, for small birds feeding on short grass). Endangered species LOCs are exceeded for birds for many of the uses in this screening-level assessment (RQs range from 0.1 to 2.49).

The chronic LOCs are also exceeded for all modeled food categories at maximum residues and based on a bobwhite quail avian reproduction study (NOAEC of 387 ppm). RQs range from 0.2 to 3.6. The screening-level assessment assumes that 100 percent of the diet is comprised of single food types with maximum residues. This assumption may not be realistic for chronic exposures, because diets are likely to vary over a longer period of time. Table 15, below summarizes the maximum acute and chronic avian RQs across different weights of birds and various food items.

Table 15. Summary of Estimated Avian Acute and Chronic Risk Quotients for Selected DCNA Uses

Site	Application Rate (lbs. ai/A)	Number of Applications	Application Interval, in days	Range of RQs	
				Acute	Chronic
Carrots	2	2	7	0.01 - 1.6	0.2 - 2.3
Celery, Carrots Lettuce, Peanuts	4	1	N/A	0.1 - 1.7	0.2 - 2.4
Potatoes	1.5	5	7	0.02 - 2.5	0.2 - 3.6
Snap beans	3.75	1	N/A	0.01 - 1.6	0.2 - 2.3

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ii. Mammals

The acute mammalian risk assessment is based on a rat acute oral LD_{50} of 3400 mg/kg. The dose-based RQs are calculated using a body weight-adjusted and consumption-weight equivalent dose. Acute dose-based RQ values for mammals do not exceed the acute LOC following single or multiple applications of DCNA. The RQs exceed the listed-species acute risk LOC (0.1) for small- and intermediate-sized (15- and 100-gram) mammals that feed on short grass.

Chronic RQs exceed the chronic risk LOC for all modeled food types except for seeds, based on a chronic and reproductive study with a NOAEC of 250 mg/kg-diet (RQs range from 0.2 to 48). The screening-level assessment assumes that 100 percent of the diet is comprised of single food types foraged only from treated fields. The assumption of 100 percent diet from a single food type may not be realistic for chronic exposures because diets are likely to be more variable over longer periods of time depending on size and forage range of animals. Table 16, below, provides the predicted chronic mammalian RQs.

Table 16. Summary Estimated Chronic Mammalian RQs from Single and Multiple Applications of DCNA

Site	App. Rate lbs. ai/A	Number of Applications	Application Interval, in days	Range of Chronic RQs
Carrots	2	2	7	0.2 - 31
Celery, Carrots Lettuce, Peanuts	4	1	N/A	0.2 - 33
Potatoes	1.5	5	7	0.3 - 48
Snap beans	3.75	1	N/A	0.2 - 31

iii. Non-Target Insects

EPA does not currently quantify risks to terrestrial non-target insects. RQs are therefore not calculated for these organisms. Since DCNA is practically non-toxic to bees on a contact exposure basis (LD_{50} of >181.29 μg/bee), the potential for DCNA to have adverse effects on pollinators and other beneficial insects is low.

iv. Terrestrial Plants

No acute or chronic non-target terrestrial or semi-aquatic plant data were presented; therefore risks to non-target terrestrial plants cannot be assessed. However, the Agency believes that the potential for non-target terrestrial plant risk is low. DCNA is applied directly to a variety of growth stages of terrestrial plants and to potato seed pieces with no reported adverse phytotoxicity effects. Tier 1 terrestrial plant toxicity data will be required to confirm this assumption of low terrestrial plant risk.

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4. Ecological Incidents

The Agency has received no reports of ecological incidents for DCNA.

5. Endangered Species Concerns

The Agency's screening level ecological risk assessment for endangered species results in the determination that DCNA will have no direct acute effects on threatened and endangered freshwater aquatic invertebrates or aquatic plants. The assessment indicates that DCNA has the potential to affect listed freshwater fish, birds, and mammals should exposures occur at the estimated levels. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act.

At this time, the Agency cannot quantitatively predict potential effects to endangered and threatened marine/estuarine aquatic organisms or terrestrial plants due to a lack of toxicity studies on these organisms. Further, potential indirect effect to any species dependent upon a species that experiences effects cannot be precluded from use of DCNA.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not 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 to support reregistration of products containing DCNA (dicloran) as an active ingredient.

The Agency has completed its review of submitted data and its assessment of the human health risk, occupational exposure and risk, and ecological risk associated with the use of pesticide products containing the active ingredient DCNA. Based on a review of these data, the Agency has sufficient information on the human health and ecological effects of DCNA to make decisions as part of the tolerance reassessment process under FFDCA and the reregistration process under FIFRA, as amended by FQPA. The Agency has determined that DCNA-containing products are eligible for reregistration provided that: (i) required product-specific data are submitted; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of DCNA that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination for reregistration eligibility of DCNA, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of DCNA, the Agency has determined that DCNA products, unless labeled and used as specified in this document, would present risks inconsistent with

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FIFRA and FFDCA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of DCNA. If all changes outlined in this document are incorporated into the product labels, then all current risks for DCNA will be adequately mitigated for the purposes of this determination under FIFRA. Once the endangered species assessment is completed, further changes to these registrations may be necessary as explained in section IV.D.4.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for DCNA. During the public comment period on the risk assessments, which closed on January 17, 2006, the Agency received comments from one private citizen and the technical registrant, Gowan Company. These comments are available in the public docket (EPA-HQ-OPP-2005-0265) at http://www.regulations.gov. A Response to Comments document is available in the public docket as well.

The RED and technical supporting documents for DCNA are available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket identification (ID) number EPA-HQ-OPP-2005-0265. The public may access EPA Dockets at http://www.regulations.gov/fdmspublic-rel11/component/main. In addition, the DCNA RED may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with DCNA. EPA has determined that risk from dietary (food plus drinking water) exposure to DCNA fits within its own "risk cup." An aggregate assessment was conducted for exposures through food and drinking water uses (DCNA is not registered for residential use), and the Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for DCNA meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and water.

b. Determination of Safety to the U.S. Population

The Agency has determined that the established tolerances for DCNA meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is

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a reasonable certainty no harm will result to the general population, infants, and children, or any other population subgroups from the use of DCNA. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of DCNA. As discussed in section 3, the total acute and chronic dietary (food plus water) risks are below the Agency's level of concern (< 100% of the PAD) for the general population and all subgroups. The highest exposed population subgroups (when assessing the aggregate dietary exposure) were females (13-49 years old) at 52% of the aPAD and children (1-2 years old) at 15% of the cPAD.

c. Determination of Safety to Infants and Children

The Agency has determined that the established tolerances for DCNA meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty that no harm will result to infants and children. The safety determination for infants and children considers the toxicity, use practices, and environmental behavior noted for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of DCNA residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from DCNA residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The 10x FQPA safety factor has been retained for acute and chronic exposures due to a lack of a DNT study in the toxicology database for DCNA.

As discussed in section 3, the total acute and chronic dietary (food plus water) risks are below the Agency’s level of concern (< 100% of the PAD) for the general population and all subgroups.

d. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that EPA include evaluations of potential effects in wildlife. In regards to pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. Furthermore, as the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP) and DCNA may be subject to additional screening.

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e. Cumulative Risks

Risks summarized in this document are those that result only from the use of DCNA. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for DCNA. Therefore, for the purposes of this decision, EPA has not assumed that DCNA shares a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

2. Tolerance Summary

Tolerances for DCNA in/on plant and livestock commodities (40 CFR § 180.200) are presently expressed in terms of the parent compound in all registered or rotated crops.

a. Tolerances Currently Listed Under 40 CFR §180.200

Tolerances are currently established under 40 CFR §180.200 for residues of DCNA [2,6-dichloro-4-nitrobenzenamine (CAS) 99-30-9] per se in/on the following raw agricultural commodities. Unless otherwise specified, the tolerances in Table 17 provide for residues from pre-harvest applications. The Agency has concluded that the residue of concern for tolerance enforcement purposes is DCNA only.

Additional residue data are necessary to establish certain revised DCNA tolerance values. EPA notes that while additional data are needed to support these revised tolerances, there are no dietary risks associated with these tolerances and EPA considers them reassessed at the current levels.

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Table 17. Tolerance Summary for DCNA

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments (correct commodity definition)
Tolerances listed under 40 CFR §180.200			
Apricot, post-harvest	20	TBD[1]	[Apricot]
Bean, Snap, succulent	20	20	The maximum residues of DCNA in/on snap and succulent beans from trials approximating the registered label rate is <18.30 ppm. The reassessed tolerance is harmonized with the Canadian MRL; no Codex MRL is established for DCNA on snap beans.
Carrots, roots, post-harvest	10	10	The calculated residues of DCNA from trials reflecting the registered post-harvest rate at 1x ranged from 2.66 to 9.24 ppm. The reassessed tolerance is harmonized with Codex MRL.
Celery	15	15	[Celery]
Cherry, sweet, post-harvest	20	TBD[1]	[Cherry, sweet]
Cucumber	5	2	The maximum residue of DCNA in/on cucumbers from trials approximating current label use pattern is <1.92 ppm. The reassessed U.S. tolerance level is not in harmony with the Canadian MRL of 0.5 ppm presumably due to differences in registered uses and good agricultural practices; no Codex MRL has been established for DCNA on cucumber.
Endive (escarole)	10	Revoke	A leafy vegetable subgroup tolerance will be established.
Garlic	5	TBD[1]	
Grape	10	10	The maximum residues of DCNA in/on grapes from trials approximating the registered label rate is <3.86 ppm. These data suggest that the established grape tolerance of 10 ppm could be lowered. HED, however, is reassessing the grape tolerance at 10 ppm to remain harmonized with Codex.
Lettuce	10	Revoke	A leafy vegetable subgroup tolerance will be established.

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Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments (correct commodity definition)
Nectarine, post-harvest	20	TBD[1]	The requested data for peach may be translated to nectarine. When the requested data for peaches have been submitted and reviewed, EPA will examine whether the nectarine tolerance could be revoked as per 40 CFR §180.1(h). [Nectarine]
Onion	10	TBD[1]	
Peach, post-harvest	20	TBD	[*Peach*]
Plum, prune, fresh, post-harvest	15	TBD	[*Plum*]
Potato	0.25	0.25	The maximum residues of DCNA in/on potatoes from trials reflecting a 20-day PHI and label rate is 0.22 ppm. The potato tolerance is reassessed at the same level pending label revision to specify a 20-day PHI.
Rhubarb	10	TBD[1]	
Sweet potato, post-harvest	10	TBD[1]	[*Sweet potato*]
Tomato	5	TBD[1]	
Tolerances to be added under 40 CFR §180.200			
Fennel	None	TBD[1]	A tolerance must be established for fennel. Typically EPA allows for translation of data from celery to fennel. But for DCNA, the use patterns for fennel differ from celery, and therefore translation is not an option.
Vegetable, Leafy (except *Brassica* and spincach), Subgroup 4a	none	10	The maximum residues of DCNA in/on lettuce from trials reflecting current label use pattern is <4.89 ppm. These data suggest that the established lettuce tolerance of 10 ppm could be lowered. EPA, however, is reassessing the lettuce tolerance at 10 ppm to remain harmonized with Codex.

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Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments (correct commodity definition)
Shallot	none	TBD[1]	A tolerance must be established for shallot. Typically EPA allows for translation of data from onion to shallot. But for DCNA, the use patterns for shallot differ from onion, and therefore translation is not an option.

[1]TBD = To be determined. Additional data are required for tolerance reassessment. Note that while additional data are needed, there are no dietary risks associated with these tolerances and EPA considers them reassessed at current levels.

b. Codex/International Harmonization

The Codex Alimentarius Commission and Canada have established maximum residue limits (MRLs) for residues of DCNA in/on various plant commodities. The Codex and Canadian MRLs are expressed in terms of DCNA *per se*, which is identical to the U.S. tolerance expression.

The current or reassessed U.S. tolerances are harmonized with the Codex MRLs for all commodities except for plums (including prunes). The U.S. tolerance for plums (including prunes) is higher than the Codex MRL because EPA has reviewed residue data that supports the higher tolerance level. The U.S. tolerances are harmonized with the Canadian MRLs for all commodities except for carrots and cucumbers. For both commodities, the U.S. tolerances are higher than the Canadian MRLs because EPA has reviewed residue data that supports the higher tolerance levels.

D. Regulatory Rationale

1. Human Health Risk Management

a. Dietary Risk Mitigation

EPA conducted refined acute and chronic dietary exposure assessments for DCNA using PDP data for all commodities except rhubarb, assuming that non-detectable residues are at the limit of detection and assuming 100% crop treated. At the 99.9th percentile of exposure, the estimated exposure for food and water was 52% of the aPAD (females ages 13-49) and 15% of the cPAD (children ages 1-2) (the most highly exposed population subgroup). These estimates are below the Agency's level of concern, and therefore no dietary risk reduction measures are required.

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b. Aggregate Risk Mitigation

EPA must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential. DCNA has no residential uses. Therefore, the aggregate assessments for DNCA consider exposures and risks from food and drinking water.

Acute and chronic aggregate exposure estimates for food and drinking water are below EPA's level of concern for all population subgroups. At the 99.9th percentile of exposure, the estimated food and water exposure for females 13-49 years old accounted for 52% of the aPAD. For chronic exposures, the most highly-exposed subgroup was children 1-2 years old, with exposures accounting for 15% of the cPAD. Therefore, no mitigation is required.

c. Occupational Risk Mitigation

i. *Handler Exposure*

EPA completes handler exposure assessments by using a baseline (long-sleeved shirt and long pants) exposure scenario. If required, increasing levels of mitigation such as personal protective equipment (PPE) and engineering controls are incorporated to achieve an adequate margin of exposure (MOE). Most DCNA handler scenarios yield MOEs greater than 100 with single layer PPE (long-sleeved shirt, long pants, and chemical-resistant gloves). In particular, no additional mitigation beyond single layer PPE is required for the DCNA liquid formulations. However, additional mitigation is required for the DCNA dust products and the wettable-powder formulations that are not packaged in water-soluble bags, in order to achieve MOEs greater than 100.

To reduce risks of concern associated with the DCNA dust products, all dust products except for Botran 6% Dust (EPA Reg 10163-188) will be voluntarily cancelled. Furthermore, the following additional mitigation is required for the Botran 6% Dust product:

- Aerial application is prohibited;
- PF10 respirators are required for mixers and loaders; and
- Enclosed cabs that provide both dermal and inhalation protection are required for ground application equipment.
- Alternatively, standard enclosed cabs providing only dermal protection may be used if applicators wear PF10 respirators within the cab.

For the DCNA wettable-powder formulations, no additional mitigation is required for products that are incorporated in water-soluble bags. However, in order to reduce risks of concern associated with the DCNA wettable powder products that are not packaged in water-soluble bags, the following mitigation is required:

- Aerial and chemigation methods of application are prohibited; and
- PF10 respirators are required for mixers and loaders.

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ii. *Post-application Risk Mitigation*

EPA is requiring lower maximum application rates for the following crops to mitigate post-application risks: grapes, snap beans, evergreen trees, and deciduous tree fruit (apricots, peaches, nectarines, plums, prunes, and sweet cherries). The required rate reductions will result in acceptable MOEs for all crops except for grapes. Table 18, below, lists the new rates for these crops.

For grapes, a longer REI is required. The new REI for grapes is 14 days, based on risk estimates for the exposure activities of leaf pulling, thinning, pruning, training, and tying, which are the highest exposure activities following cane turning and girdling (please see the discussion below regarding additional mitigation for the cane turning and girdling). The MOE for leaf pulling, thinning, pruning, training, and tying is 64 on day zero, and is above 100 within 13 days of application. Based on the risk estimates, EPA has determined that an REI of 14 days for grapes will protect workers from unacceptable post-application risks. In addition, the Agency is requiring a dislodgeable foliar residue (DFR) study on grapes treated with Botran 6% Dust to confirm the Agency's decision about potential post-application risks to workers from grapes.

For grapes, in addition to requiring a lower maximum application rate and longer REI, the post-application activities of cane turning and girdling are prohibited for 30 days following application of DCNA. The high-exposure activities of cane turning and girdling result in unacceptable risks to workers who perform the tasks within 30 days of DCNA application (the MOE for cane turning and girdling grapes is 32 at day zero, and it does not reach 100 until 32 days after application). Based on the risk estimates, cane turning and girdling grapes is prohibited for 30 days following the application of DCNA.

Table 18, below, lists the crops for which lower maximum application rates and/or longer REIs are required, and provides the MOEs that result from the mitigation.

Table 18. New Maximum Application Rates and REIs for Crops Requiring Post-Application Risk Mitigation and Resulting MOEs for the Highest Exposure Activity

Crop Group	Crops	Current Max. Rate (lb ai/acre)	New Max. Rate (lb ai/acre)	MOE at Day Zero	Number of Days Until MOE>100	Current REI	New REI
Grapes	Grapes	3.5	1.5	64[1]	13	12 hours	14 days
Tree, Fruit, Deciduous	Apricots, peaches, nectarines, plums, prunes, sweet cherries	4	1.5	106	n/a	12 hours	
Field/Row Crops, Low/Medium	Snap Beans	3	2	95	2	12 hours	
Evergreen Trees	Conifers, Christmas Trees	2	1.5	110	n/a	12 hours	

[1] The MOE of 64 on day zero corresponds to the post-application activities of leaf pulling, thinning, pruning, training, and tying. For the higher-exposure activities of cane turning and girdling, the MOE=32 on day zero, and the MOEs remain below 100 until 32 days after application. Based on these risk estimates, the Agency is prohibiting cane turning and girdling grapes for 30 days following application of DCNA.

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The Agency's post-application exposure assessment resulted in MOEs below 100 at day zero for potatoes (MOE=70), celery (MOE=80), lettuce (MOE=80), onions (MOE=80), garlic (MOE=80), shallots (MOE=80), and snap beans (MOE=95). The Agency has concluded that it is likely that the post-application exposure assessment overestimates the post-application risks from DCNA due to the underlying toxicity endpoint. The post-application exposure assessment is based on a 21-day dermal study in rabbits (MRID 40555101) with a NOAEL of 120 mg/kg/day and a LOAEL of 1200 mg/kg/day, which is above the limit dose of 1000 mg/kg/day. The nature of the effects observed at the LOAEL (a 13 percent increase in adrenal weight relative to control) was not severe, and was observed only in males. Due to the widely-spaced dosing regime in this study, it is likely that that true NOAEL is higher than 120 mg/kg/day. If, for example, the true NOAEL is 150 mg/kg/day, then the MOEs for celery, lettuce, onions, garlic, and shallots would be 100 on day zero. Recognizing that the true NOAEL is likely to be at least 150 mg/kg/day given the ten-fold difference between the NOAEL and LOAEL, the Agency has concluded that no post-application risk mitigation is required for root vegetables (potatoes, onions, garlic, and shallots), leafy vegetables (celery and lettuce), or low/medium field/row crops (snap beans).

The Agency is currently reviewing additional data developed by the Agricultural Reentry Task Force (ARTF) that may help to further refine the post-application exposure assessment for DCNA. Preliminary indications are that the post-application risk estimates for several exposure scenarios may be lower using the new ARTF data.

Current DCNA labels specify a REI of 12 hours. The current REIs will remain the same for all DCNA uses except for grapes. The required new REI for grapes is 14 days, to mitigate post-application risks, as discussed above.

2. Environmental Risk Mitigation

EPA's screening level ecological risk assessment shows some exceedances of the acute and chronic LOCs for birds and the chronic LOCs for mammals. The reductions in application rates associated with the occupational risk mitigation will result in lower ecological exposures for some uses. Some screening level exceedances will remain, but the Agency is not requiring additional mitigation at this time.

3. Other Labeling

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing DCNA. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

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4. Endangered Species Program

The Agency's screening level ecological risk assessment for endangered species results in the determination that DCNA will have no direct acute effects on threatened and endangered freshwater aquatic invertebrates or aquatic plants. However, the Agency's level of concern was exceeded for endangered freshwater fish, birds, mammals, and non-target terrestrial plants. Further, potential indirect effect to any species dependent upon a species that experiences effect cannot be precluded from use of DCNA. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationships between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in limitations on the use of DCNA, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of DCNA "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services' regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to DCNA at levels of concern. EPA is not requiring specific DCNA label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

V. What Registrants Need to Do

The Agency has determined that DCNA is eligible for reregistration provided that product-specific data are submitted and the mitigation measures stated in this document are included in upcoming label submissions. In the near future, the Agency intends to issue Data Call-In (DCI) notices requiring product-specific data and generic confirmatory data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific

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data, the registrant will have 8 months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Listed below are the additional generic data that the Agency intends to require.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of DCNA for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below, in Tables 19 and 20, are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 19. Toxicology, Residue Chemistry, and Occupational Exposure Data Requirements

Study Required	Guideline Number
Developmental Neurotoxicity Study (rats)	870.6300
28-day Inhalation Toxicity Study (rats)	870.3465
Nature of the Residue, Livestock (Storage stability data only)	860.1300
Residue Analytical Methods, Plant and Livestock*	860.1340
Multi-residue Method*	860.1360
Storage Stability Data, Plant, for DCHA	860.1380
Meat/Milk/Poultry/Eggs (Ruminant feeding study)	860.1480
Crop Field Trials monitoring for residues of DCNA and DCHA • Additional data are required for the reassessment or establishment of tolerances for apricot, cherry (sweet), fennel, garlic, onion, peach, plum, rhubarb, shallot, sweet potato, and tomato • Limited magnitude of the residue studies are required for all registered crops • The potato field trials must also monitor for residues of Unknown 1	860.1500
Processed Food/Feed	860.1520
Field Accumulation in Rotational Crops	860.1900
Dislodgeable Foliar Residue Study on Grapes with Botran 10% Dust formulation	875.2100

* Reserved pending results of ruminant feeding study

Table 20. Environmental Fate and Ecological Toxicity Data Requirements

Study Required	Guideline Number
Aerobic Aquatic Metabolism	835.4300
Aquatic Field Dissipation	835.6200
Accumulation – Aquatic Non-target Organisms	850.1950
Droplet Size Spectrum	840.1100
Drift Field Evaluation	840.1200

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Study Required	Guideline Number
Avian Reproduction Mallard duck	850.2300
Estuarine/Marine Fish Acute LC_{50} (Sheepshead minnow)	850.1075
Estuarine/Marine Acute Invertebrate LC_{50} (Mysid)	850.1025
Freshwater Fish Early Life Stage (Rainbow Trout)	850.1300
Estuarine/Marine Life Cycle (Mysid)	850.1450
Freshwater Fish full Life Cycle (Fathead Minnow)	850.1500
Tier I Terrestrial Plant	850.4025

2. Labeling for Manufacturing Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling outlined in Table 21.

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

A product-specific data call-in, outlining specific data requirements, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Table 21 describes the required labeling changes.

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Labeling Changes Summary Table [Attachment III]

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 21: Summary of Labeling Changes for DCNA (Dicloran)

Description	Amended Labeling Language	Placement on Label
	Manufacturing Use Products	
For all Manufacturing Use Products	"Only for formulation into a ***fungicide*** for the following pre-harvest uses apricots, beans (snap), celery, cherries (sweet), cucumbers, endive (escarole), fennel, garlic, grapes, lettuce (head and leaf), nectarines, onions, peaches, plums (fresh prunes), potatoes, rhubarb, shallots, tomatoes, Christmas trees, conifers, and potted plants/ornamentals. Post-harvest uses include carrots and sweet potatoes."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to fish." "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the	Precautionary Statements

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Description	Amended Labeling Language	Placement on Label
	requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment and washwaters."	
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] For Wettable Powder Formulations Not Packaged in Water-Soluble Bags	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators and other handlers must wear: long-sleeve shirt and long pants, chemical-resistant gloves (except applicators using motorized ground equipment, flaggers and pilots), shoes plus socks." "Mixer/loaders supporting groundboom and airblast applications must wear at least a half-face NIOSH-approved respirator with: • a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C; or • a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14g; or • a cartridge or canister with any N, R, P, or HE filter. A quarter-face cup-style dust/mist filtering respirator is not permitted." "See engineering controls for additional requirements"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

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Description	Amended Labeling Language	Placement on Label
PPE Requirements Established by the RED[1] For Wettable Powder Formulations packaged in Water Soluble Bags	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "Mixer, loaders, applicators and other handlers must wear: Long-sleeve shirt and long pants, chemical-resistant gloves (except for applicators using motorized ground equipment, flaggers and pilots), and shoes plus socks." "See engineering controls for additional requirements"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] For Dust Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All loaders, applicators and other handlers must wear: Long-sleeve shirt and long pants, chemical-resistant gloves (except for applicators using ground equipment), shoes plus socks. In addition, loaders supporting ground equipment applications must wear a NIOSH-approved half-face, full-face or hood-style respirator with: • a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C; or • a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G); or • a cartridge or canister with any N, R, P, or HE filter."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

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Description	Amended Labeling Language	Placement on Label
	"See Engineering controls for additional requirements"	
PPE Requirements Established by the RED[1] For Liquid Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators and other handlers must wear: long-sleeve shirt and long pants, chemical-resistant gloves (except for applicators using motorized ground equipment, flaggers and pilots), shoes plus socks." "See Engineering controls for additional requirements"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Control Statements for Wettable Powder Products Not Packaged in Water Soluble Bags are not required.		
Engineering Controls	"Engineering Controls	Precautionary Statements: Hazards to

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Description	Amended Labeling Language	Placement on Label
For Wettable Powder Formulations in Water Soluble bags	Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]. Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must: • wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders; and • be provided, and must have immediately available for use in an emergency such as a broken package, spill, or equipment breakdown: chemical-resistant footwear and the respirator type specified in the PPE section of this label."	Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
Engineering Controls For Dust Formulations	"Engineering Controls Applicators using motorized ground equipment must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must: • wear long-sleeve shirt, long pants, shoes, socks; and • either wear a half face NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH-approved respirator with any N, R, P or HE filter or use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified above; • be provided and have immediately available for use in an emergency when they must exit the cab in treated area: chemical-resistant gloves and, if using an enclosed cab that provides respiratory protection, a	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

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Description	Amended Labeling Language	Placement on Label
	respirator of the type specified above; • take off any PPE that was worn in the treated area before reentering the cab; and • store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."	
Engineering Controls For Liquid Formulations	"Engineering Controls Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing*. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"This pesticide is toxic to fish. This product may contaminate water through runoff. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product." "Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may	Precautionary Statements immediately following the User Safety Recommendations

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Description	Amended Labeling Language	Placement on Label
	be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment, washwaters or rinsate." "For products applied as sprays, add the following in addition to the above: This chemical can contaminate surface water through spray or dust applications. Under some conditions, it may also have a potential for runoff into surface water after application."	
Restricted-Entry Intervals	**Grapes:** "Do not enter or allow worker entry into treated areas during the restricted entry interval of 14 days when applied to grapes. Notify workers of the application by warning them orally and by posting warning signs at the entrances to treated area. Cane turning and girdling grapes is prohibited for 30 days following application of DCNA." **All of other crops and use patterns:** "For all other crops and use patterns, do not enter or allow worker entry during the restricted entry interval of 12 hours."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: Coveralls, Shoes plus socks, Chemical-resistant gloves made of any waterproof material."	Direction for Use Agricultural Use Requirements box
General 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."	Place in the Direction for Use directly above the Agricultural Use Box

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<table>
<tr><th>Description</th><th>Amended Labeling Language</th><th>Placement on Label</th></tr>
<tr><td>Other Application Restrictions (Risk Mitigation)</td><td>
Dust formulation:
“Aerial application is prohibited.”
“Application by handheld equipment is prohibited.”

Wettable Powder formulation not packaged in water soluble bags/packets:
“Aerial application is prohibited.”
“Chemigation is prohibited.”

All formulations:
Labels must be amended to reflect the following new maximum single application rates:
<table>
<tr><th>Crop Group</th><th>Crops</th><th>Maximum Single Application Rate (pounds active ingredient per acre; lb ai/acre)</th></tr>
<tr><td>Grapes</td><td>Grapes</td><td>1.5</td></tr>
<tr><td>Tree, Fruit, Deciduous</td><td>Apricots, peaches, nectarines, plums, prunes, sweet cherries</td><td>1.5</td></tr>
<tr><td>Field/Row Crops, Low/Medium</td><td>Snap Beans</td><td>2</td></tr>
<tr><td>Evergreen Trees</td><td>Conifers, Christmas Trees</td><td>1.5</td></tr>
</table>
</td><td>Directions for Use</td></tr>
</table>

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<table>
<tr><th>Description</th><th>Amended Labeling Language</th><th>Placement on Label</th></tr>
<tr><td></td><td>Labels must be amended to reflect the following maximum annual application rates (i.e., new limits on the amount that may be applied per year):

<table>
<tr><th>Crop</th><th>Maximum Annual Application Rate (lb ai/acre/year)</th></tr>
<tr><td>Potatoes</td><td>7.5</td></tr>
<tr><td>Celery, fennel</td><td>5</td></tr>
<tr><td>All other crops</td><td>4.0</td></tr>
</table>

Products labeled for use on grapes:
“Cane turning and girdling grapes is prohibited for 30 days following application of DCNA.”</td><td></td></tr>
<tr><td>Spray Drift Label Language for Products Applied as a Spray</td><td>“A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial, airblast, chemigation) can influence pesticide drift. The applicator and grower must evaluate all factors and make appropriate adjustments when applying this product.”

“Do not make any type of application into temperature inversions.”

“WIND SPEED:”
“Do not apply at wind speeds greater than 10 mph at the application site.”

“DROPLET SIZE:”
“Apply as a medium or coarser spray (ASAE standard 572).”</td><td>Directions for Use</td></tr>
</table>

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Description	Amended Labeling Language	Placement on Label
	"RELEASE HEIGHT (GROUND APPLICATION):" "Apply using a nozzle height of no more than 4 feet above the ground or crop canopy." "RELEASE HEIGHT (AERIAL APPLICATION):" "Do not release spray at a height greater than 10 feet above the ground or crop canopy." "Additional requirements for aerial applications:" "The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter." "Aerial applicators must consider flight speed and nozzle orientation in determining droplet size." "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind" "Additional requirements for airblast applications:" "Direct sprays into the canopy." "Turn off outward pointing nozzles at row ends and when spraying outer rows."	

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

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Appendix A:
Use Patterns Eligible for Reregistration

Pre-Harvest Uses

Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Field/Row Crops (Snap Beans)						
Ground Equipment	Dust	2.0	4.0	2	12	
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder not packaged in water soluble bags (non-WSB)	2.0	4.0	2	12	
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder packaged in water soluble bags (WSB)	2.0	4.0	2	12	
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	2.0	4.0	2	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Vegetable, Fruiting (Tomatoes)						
Ground Equipment	Dust	0.75	4.0	10	12	
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)					
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	0.75	4.0	10	12	
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	0.75	4.0	10	12	
Tree, Fruit, Deciduous (Plums, Prunes)						

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	1.5	4.0	10	12	
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	1.5	4.0	10	12	
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	1.5	4.0	10	12	
Tree, Fruit, Deciduous (Apricots, Peaches, Nectarines, Sweet Cherries)						
Ground Equipment	Dust	1.5	4.0	10	12	
Groundboom, Airblast,	Wettable Powder (non-WSB)	1.5	4.0	10	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Low Pressure handwand, Backpack sprayer, High Pressure Handwand						
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	1.5	4.0	10	12	
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	1.5	4.0	10	12	
Vegetable, Curcurbit (Cucumber)						
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer,	Wettable Powder (non-WSB)	1.0	4.0	1	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
High Pressure Handwand						
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	1.0	4.0	1	12	
Vegetable, Curcurbit (Rhubarb)						
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	1.0	4.0	3	12	
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	1.0	4.0	3	12	
Vegetable, Leafy, Greenhouse (Lettuce, leaf only)						
Ground Equipment	Dust	4.0	4.0	14	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	4.0	4.0	14	12	
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	4.0	4.0	14	12	
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	4.0	4.0	14	12	
Vegetable, Leafy, (Celery)						
Groundboom, Airblast,	Wettable Powder (non-WSB)	4.0	5.0	7	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Low Pressure handwand, Backpack sprayer, High Pressure Handwand						
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	4.0	5.0	7	12	
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	4.0	5.0	7	12	
Leafy, Vegetable (Fennel, Florence)						
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer,	Wettable Powder (non-WSB)	4.0	4.0	7	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
High Pressure Handwand						
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	4.0	4.0	7	12	
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	4.0	4.0	7	12	
Leafy, Vegetable (Endive)						
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	2.0	4.0	14	12	
Aerial,	Wettable Powder	2.0	4.0	14	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	(WSB)					
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	2.0	4.0	14	12	
Vegetable, Root (Sweet Potatoes)						
Seed Dip	Liquid Flowable, Wettable Powder	120	120	N/A	12	
Plantbed spray		120	120	N/A	12	
Vegetables/potatoes						
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	4.5	7.5	14-20	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Aerial, Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (WSB)	4.5	7.5	14-20	12	
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	4.5	7.5	14-20	12	
Vegetable, Root (Onions, Garlic, Shallots)						
Ground Equipment	Dust	4.0	4.0	14	12	
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	4.0	4.0	14	12	
Aerial,	Wettable Powder	4.0	4.0	14	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Chemigation, Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	(WSB)					
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	4.0	4.0	14	12	
Vine/Trellis (Grapes (various types))						
Ground Equipment	Dust	1.5	4.0	14	14 days	
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	1.5	4.0	14	14 days	
Aerial, Chemigation,	Wettable Powder (WSB)	1.5	4.0	14	14 days	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Groundboom, Low Pressure handwand, Backpack sprayer, High Pressure Handwand						
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	1.5	4.0	14	14 days	
Cut Flowers (Chrysanthemums Roses, Hydrangeas)						
Ground Equipment	Dust	0.75	4.0	N/A	12	
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	0.75	4.0	N/A	12	
Aerial, Chemigation, Groundboom,	Wettable Powder (WSB)	0.75	4.0	N/A	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Low Pressure handwand, Backpack sprayer, High Pressure Handwand						
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	0.75	4.0	N/A	12	
Ornamentals, Potted Plants (Geraniums)						
Ground Equipment	Dust	0.75	4.0	N/A	12	
Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable Powder (non-WSB)	0.75	4.0	N/A	12	
Aerial, Chemigation, Groundboom, Low Pressure handwand,	Wettable Powder (WSB)	0.75	4.0	N/A	12	

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Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/ Comments
Backpack sprayer, High Pressure Handwand						
Aerial, Chemigation, Groundboom, Airblast, Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Liquid Flowable	0.75	4.0	N/A	12	

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Post-harvest Uses

Application Type, Equipment	Formulation	Maximum Annual Application Rate (lb ai/A/year)	REI (Hours)	Restrictions/ Comments
Tree, Fruit, Deciduous (Apricots , Peaches, Nectarines, Plums, Prunes, Cherries)				
Processing line Operations, Spraying, Plant Dipping, Brushes, Hydrocooler	Wettable powder	1.5	12	
Vegetable, Root (Sweet Potatoes)				
Groundboom, Plant Dipping	Wettable powder,	4.0	12	
Aerial, Chemigation, Plant Dipping	Liquid Flowable, Wettable Powder (WSB)			
Cut Flowers (Chrysanthemums, Roses, Hydrangeas, Gladiolus)				
Ground Equipment	Dust	0.75	12	
Low Pressure handwand, Backpack sprayer, High Pressure Handwand	Wettable powder, Liquid Flowable			
Tree, Evergreen (Conifer, Christmas trees)				

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Application Type, Equipment	Formulation	Maximum Annual Application Rate (lb ai/A/year)	REI (Hours)	Restrictions/ Comments
Aerial, Low Pressure handwand, Backpack sprayer, High Pressure Handwand Plant Dipping	Liquid Flowable, Wettable Powder (WSB)	1.5	12	
Airblast, Plant Dipping	Wettable Powder,			
Vegetable, Curcurbit (Cucumber, Rhubarb)				
Low pressure handwand, High pressure Handwand, Backpack Sprayer	Wettable Powder, Liquid Flowable	1.0	12	

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Greenhouse and Hothouse Uses

Application Type, Equipment	Formulation	Maximum Annual Application Rate (lb ai/A/year)	REI (Hours)	Restrictions/ Comments
Vegetable, Curcurbit (Cucumber, Rhubarb)				
Low Pressure Handwand, High Pressure Handwand, Backpack Sprayer	Wettable Powder, Liquid Flowable,	1.0	12	
Vegetable, Leafy, Greenhouse (Lettuce, leaf only)				
Ground Equipment	Dust	4.0	12	
Groundboom, High Pressure Handwand	Wettable Powder			
Aerial, Chemigation, High Pressure Handwand	Liquid Flowable, Wettable Powder (WSB)			
Greenhouse Seed Potatoes or Transplants				
Low Pressure Handwand, High pressure Handwand, Backpack Sprayer	Wettable Powder, Liquid Flowable	4.0	12	
Vegetable, Fruiting (Tomatoes)				
Ground Equipment	Dust	0.75	12	

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Application Type, Equipment	Formulation	Maximum Annual Application Rate (lb ai/A/year)	REI (Hours)	Restrictions/ Comments
Backpack Sprayer, Low pressure Handwand, High pressure Handwand	Wettable Powder, Liquid Flowable			

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Appendix B:
Data Supporting Guideline Requirements for the Reregistration of DCNA use on Field/Row crops, Tree and Vine crops, Ornamentals, Conifers and Greenhouse Vegetables.

REQUIREMENT			CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
New Guideline Number	Old Guideline Number	Description	
875.2100	132-1A	Foliar (Dislodgeable) Residue Dissipation	45062001
ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity Test (LD50), Bobwhite Quail or Duck	43755101, 40583103
850.2200	71-2	Avian Acute Dietary Toxicity Test (LC50) Bobwhite Quail and Mallard Duck	405088-12, 43115501, 40508811, 43115502
850.2300	71-4	Avian Reproduction Test, Bobwhite Quail	46218900
850.1075	72-1	Fish Acute Toxicity Test, Freshwater Rainbow Trout and Bluegill Sunfish	00096064, 00096058
850.1010	72-2	Invertebrate Acute Toxicity Test, Daphnia Magna	40583102
850.1035	72-3c	Estuarine/marine acute invertebrate LC50 (Mollusk)	00087031
850.1300	72-4a	Daphnid Chronic Toxicity Test (early life stage in fish)	
850.1350	72-4b	Mysid (Shrimp) Chronic Toxicity Test (life cycle in aquatic invertebrates)	46657103
850.1450	72-4d	Early-life Stage Estuarine	
850.3020	141-1	Honey Bee Acute Contact Toxicity	00036935
850.4400	123-2	Aquatic Plant Toxicity Test Using *Lemma Spp*.,	46657105
870.1100	81-1	Acute Oral Toxicity Test, Rat	00086879, 00064581
870.3800	83-4	2-generation Reproduction and Fertility Effects, Rat	44414101
TOXICOLOGY			
870.1100	81-1	Acute Oral Toxicity Testing, Rat	00086879
870.1200	81-2	Acute Dermal (Skin) Toxicity Test, Rabbit/rat	00086894
870.2400	81-4	Acute (Primary) Eye Irritation, Rabbit	00086892
870.2500	81-5	Acute (Primary) Dermal (Skin) Irritation	00086893
870.2600	81-6	Dermal (Skin) Sensitization	00082721
870.4300	83-5	Combined Chronic Toxicity/carcinogenicity	46360701
870.4200b	83-2b	Carcinogenicity (Oncogenicity), Mouse	40977101
870.4100b	83-1b	Chronic Feeding Toxicity Study, Non-rodent	00029056, 00082718, 00026810, 45610801
870.3800	83-4	2-generation Reproduction and Fertility Effects, Rat	44233803, 44414101
870.3700a	83-3a	Prenatal Developmental Toxicity (Teratogenicity), Rat	46447501
870.3700b	83-3b	Prenatal Developmental Toxicity (Teratogenicity), Rabbit	43952101
870.3100	82-1a	Subchronic Oral Toxicity Test (90-day Feeding, Rodent)	00029056, 00082718, 46360702

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870.3150	82-1b	Subchronic Oral Toxicity Test (90-day Feeding, Non-Rodent)	00029056, 00026810, 00082718
870.3200	82-2	Repeated Dose Dermal Toxicity Test (21 Day, Rabbit/rat)	40555101
870.7485	85-1	Metabolism and Pharmacokinetics (General Metabolism)	44061001,43255401, 43255402
870.5265		Reverse Gene Mutation Assay	40508801, 00046435, 00046436, 00087018
870.5375	84-2b	In Vitro Mammalian Cytogenetics Tests (Structural Chromosomal Aberration Test)	40508802
870.5550	84-2	Unscheduled DNA Synthesis in Mammalian Cells in Culture	40619001
ENVIRONMENTAL FATE			
835.2120	161-1	Hydrolysis of Parent and Degradates as a Function of pH at 25°C (Hydrolysis)	144957 (Acc. No. 253963)
835.2240	161-2	Direct Photolysis Rate in Water by Sunlight (Photodegradation in sunlight)	43891901, 40508809
835.2410	161-3	Photodegradation of Parent and Degradates in Soil (Photodegradation in soil)	43893601, 40508810
835.4100	162-1	Aerobic Soil Metabolism Study	40894801, 00086942
835.4200	162-2	Anaerobic Soil Metabolism Study	40894801
835.4400	162-3	Anaerobic Aquatic Metabolism Study	46216001, 46657101, 43866501
835.4300	162-4	Aerobic Aquatic Metabolism Study	46216001, 46657101
835.1240/1230	163-1	Anaerobic Aquatic Metabolism Study	40538202, 40538201, 43809001, 40863001, 00065859
835.6100	164-1	Terrestrial Field Dissipation Study	44414201, 40583101, 00086953, 00086955, 00082668
850.1730	165-4	Fish BCF (aquatic organism accumulation study)	43782001, 40508808
835.7100	166-1	Small Scale Prospective Ground Water Monitoring Study	45237401
RESIDUE CHEMISTRY			
860.1300	171-4A	Nature of Residue - Plants	00029049, 00077903, 00086923, 00086924, 00095972, 40982301, 41180801, 44237801, 44245201
860.1300	171-4B	Nature of Residue - Livestock	00096027, 00127891, 4050884, 4050884, 40508806, 40645401, 41382401, 44050201, 44071901
860.1340	171-4C	Residue Analytical Method - Plants	00029037, 00029041, 00029043, 00029048, 00046626, 00078882, 00079872, 00081770, 00083534, 00086910, 00086912, 00086914, 00095984, 00095988, 00096004, 40508814, 44099301[i]

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REQUIREMENT			CITATION(S)
860.1340	171-4D	Residue Analytical Method - Animals	40785401, 41687401, 45492601
860.1360	171-4M	Multiresidue Method	43508901
860.1380	171-4E	Storage Stability Data - Plant	00082667, 00095978, 00095998, 43975401, 44258801, 45159801
860.1380	171-4E	Storage Stability Data - Animal	00086897, 00087015, 00095934 00098563, 41149701, 41852401
860.1480	171-4J	Magnitude of Residues in Meat, Milk, Poultry and Eggs	00086897, 00087015, 00095934, 00098563
860.1500	171-4K	Crop Field Trails (Carrot)	44020701
860.1500	171-4K	Crop Field Trails (Potato)	00141160
860.1500	171-4K	Crop Field Trails (Onion)	40508817
860.1500	171-4K	Crop Field Trails (Celery)	00096021, 00096035
860.1500	171-4K	Crop Field Trails (Rhubarb)	00029052
860.1500	171-4K	Crop Field Trails (Lettuce)	00029048, 00086916, 00095970
860.1500	171-4K	Crop Field Trails (Beans, snap, succulent)	00096026
860.1500	171-4K	Crop Field Trails (Tomato)	00029046, 00029055, 00046625 00046626, 00068494, 00078882 00082658, 00086045, 00095971 00095992, 00095995, 45265001
860.1500	171-4K	Crop Field Trails (Cucumber)	00096023
860.1500	171-4K	Crop Field Trails (Apricot)	00029043
860.1500	171-4K	Crop Field Trails (Cherry, Sweet)	00029043, 00082705
860.1500	171-4K	Crop Field Trails (Nectarine)	00081771, 00096052, 00096801
860.1500	171-4K	Crop Field Trails (Peach)	0002904, 40508815, 43952102
860.1500	171-4K	Crop Field Trails (Plum)	00071489, 00086917, 00086962 00095963, 00095973, 00095974 00096007, 00096016, 00096019 00096024, 40508816, 43933001
860.1500	171-4K	Crop Field Trails (Cotton, undelinted seed and gin byproducts)	00061543, 00092439, 00095964 00095997, 00096022
860.1500	171-4K	Crop Field Trails (Grape)	00080893, 00095963, 00095994
860.1500	171-4K	Crop Field Trails (Kiwifruit)	00046626, 00078881, 00078882 00096077, 00140141, 00140142
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed - Grape	40508819, 43954601
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed - Plum	43952104
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed - Potato	43928001
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed - Tomato	43952103

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REQUIREMENT			CITATION(S)
860.1850	165-1	Confined Accumulation in Rotational Crops Study	44348201
860.1900	165-2	Field Accumulation in Rotational Crops Study	45159801

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Appendix C:
Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in 2777 Crystal Drive (One Potomac Yard) Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:30 PM.

The docket initially contained preliminary human health and ecological effects risk assessments and related documents that were published November 16, 2005. The public comment period closed sixty (60) days later on January 16, 2006. The EPA then considered comments and revised the risk assessments where appropriate. Final human health, and ecological risk assessments, as well as additional support documents, will be published in the docket with this RED. These documents include the following:

HED Documents:

- Dicloran: Revised Chapter of the Reregistration Eligibility Decision Document (RED). (Toiya Goodlow, Byong-Han Chin, Christine L. Olinger, Timothy Dole and Matthew G. Lloyd, 5/11/2006)

- Revised Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision. (Matthew G. Lloyd and Timothy Dole, 06/13/2006)

- Dicloran (DCNA) Revised Acute and Chronic Dietary Exposure Assessment for Reregistration Eligibility Decision (Christine L Olinger, 03/23/2006)

- Dicloran (DCNA). Residue Chemistry Considerations for the Reregistration Eligibility Decision (RED) Document. Summary of Analytical Chemistry and Residue Data (Christine L. Olinger, 08/09/2005)

EFED Documents:

- Revised Ecological Risk Assessment in Support of the Reregistration Eligibility Decision on DCNA (Dicloran) (Cheryl A. Sutton and Christopher J. Salice (02/07/2006)

- DCNA (Dicloran): Revised Tier I Drinking Water EDWC's for Use in the Human Health Risk Assessment (Cheryl A. Sutton, 01/24/2006)

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Appendix D.
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43755101	Rodgers, M. (1995) Dicloran Technical: Acute Oral Toxicity (LD50) to the Bobwhite Quail: Lab Project Number: GWN 2: GWN 2/951332. Unpublished study prepared by Huntingdon Research Centre Ltd. 27 p.
43782001	Schocken, M. (1995) Bioconcentration/Metabolism Study With (Carbon 14)DCNA in Bluegill Sunfish: Final Report: Lab Project Numbers: 95-6-5940: 12791.0494.6102.140. Unpublished study prepared by Springborn Labs., Inc. 132 p.
43809001	Wisocky, M. (1995) Aged Leaching of (carbon 14) Dicloran in Four Soils: Lab Project Number: XBL94112: RPT00236: F94146-015. Unpublished study prepared by XenoBiotic Labs, Inc. 209 p.
43866501	Wisocky, M. (1995) Anaerobic Aquatic Metabolism of (carbon 14)- Dicloran: Lab Project Number: XBL94111: RPT00235. Unpublished study prepared by XenoBiotic Labs, Inc. 153 p.
43891901	Misra, B. (1995) 2,6-Dichloro-4-Nitroaniline (DCNA): Photodegradation of DCNA in an Aqueous Buffered Solution Under Artificial Sunlight: Final Report: Lab Project Number: ME 9500194. Unpublished study prepared by Pittsburgh Environmental Research Lab, Inc. 84 p.
43893601	Misra, B. (1995) 2,6-Dichloro-4-Nitroaniline (DCNA): Photodegradation of DCNA on

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	Soil Under Artificial Sunlight: Final Report: Lab Project Number: ME 9500193. Unpublished study prepared by Pittsburgh Environmental Research Lab, Inc. 85 p.
43928001	Kliskey, E. (1996) Determination of the Magnitude of Residues of Dicloran (DCNA) in Potato Processed Fractions Resulting from Foliar Applications of Botran 75W: Lab Project Number: 95013: 66008. Unpublished study prepared by Compliance Services Int'l.; Agivse Laboratories; and Wm. J. Englar & Associates, Inc. 148 p.
43933001	Kliskey, E. (1996) Determination of the Magnitude of Residues of DCNA in Plum RAC's Resulting from Foliar Applications of Botran 75W Plus Post-Harvest Sprays of Allisan: Lab Project Number: 95008: 66009. Unpublished study prepared by Compliance Services Int'l. and Research for Hire, Inc. 134 p.
43952101	Wilcox, S.; Barton, S. (1996) Dicloran: Developmental Toxicity Study in Rabbits: Lab Project Number: 11379: 491294: IRI 491294. Unpublished study prepared by Inveresk Research International. 68 p.
43952102	Kliskey, E. (1996) Determination of the Magnitude of the Residues of DCNA in Peach RAC's Resulting from Foliar Applications of Botran 75W Plus a Post-Harvest Dip of Allisan: Lab Project Number: 95007: 95007-CA1: 95007-NC1. Unpublished study prepared by Compliance Services International. 172 p.
43952103	Kliskey, E. (1996) Determination of the Magnitude of the Residues of DCNA in Tomato Processed Fractions Resulting from Foliar Applications of Botran 75W to Tomato Plants: Lab Project Number: 95010: 95010-CA1. Unpublished study prepared by Compliance Services International. 166 p.
43952104	Kliskey, E. (1996) Determination of the Magnitude of the Residues of DCNA in Dried Prune Processed Fractions Resulting from Foliar Applications of Botran 75W: Lab Project Number: 95011: 95011-CA1. Unpublished study prepared by Compliance Services International. 150 p.
43953401	Coody, P. (1996) Candidate Site Selection Study: Botran: Field Scale Groundwater Monitoring: Lab Project Number: 112217-20-4187: 113260-16-4187: JOB # H5054. Unpublished study prepared by Weber, Hayes, and Associates. 95 p.
43954601	Kliskey, E. (1996) Determination of the Magnitude of Residue of Dicloran (DCNA) in Grape Processed Fractions Resulting from Foliar Applications of Botran 75W: Lab Project Number: 95012: 66009: 95012-CA1. Unpublished study prepared by Compliance Services International. 190 p.
43975401	Kemman, R. (1996) Determination of the Frozen Stability of DCNA in Lettuce and Carrot Roots: Six-month Interim Report: Lab Project Number: 95033: CSI 95033. Unpublished study prepared by Compliance Services Int'l. 81 p.
44020701	Kliskey, E. (1996) Determination of the Magnitude of Residues of Dicloran (DCNA) in Carrot RAC's Resulting from Foliar Applications of Botran 75W: Lab Project Number: 95031: CSI-020-01: 66009. Unpublished study prepared by Compliance Services Int'l. 268 p.
44020702	Upjohn (1984) Residue Determination for U-2069 (Dichloran) in Carrots (California): Lab Project Number: R 251: R251: 217-9760-154. Unpublished study. 21 p.
44020703	Upjohn (1983) Residue Determination for DCNA (2,6-Dichloro- 4-nitroaniline) in Carrots Treated with Botran 75W: Lab Project Number: R 238: R238: 24852. Unpublished study. 18 p.
44050200	Gowan Co. (1996) Submission of Metabolism Data in Support of Registration

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	Standard for DCNA (Dicloran). Transmittal of 1 Study.
44050201	Cheng, T. (1996) Nature of the Residue of (carbon 14)-Dicloran (BOTRAN TECHNICAL) in Laying Hens: Final Report: Lab Project Number: HWI 6564-100: AM 022. Unpublished study prepared by Hazleton Wisconsin, Inc. 143 p.
44055801	Hansen, M. (1985) DCNA: Residue Chemistry: Carrot Fungicide Trial 1983-1984 (California): Lab Project Number: R254. Unpublished study prepared by Tuco Div. of Upjohn Co. 18 p.
44061001	Cheng, T. (1996) Metabolism of (carbon-14)-Dicloran (Botran Technical) in Rats: Final Report: Lab Project Number: HWI 6564-108. Unpublished study prepared by Hazleton Wisconsin, Inc. 123 p.
44068001	Hayes, J.; Hoban, P.; Bierman, A. (1996) Small Scale Prospective Groundwater Study for BOTRAN 75W (DCNA) Applied to Head Lettuce in Monterey County, California: Phase I: Site Characterization and Conceptual Model: Lab Project Number: 961: H5054: H5054.B. Unpublished study prepared by PTRL East, Inc. and Weber, Hayes and Associates. 196 p.
44071901	Cheng, T. (1996) The Nature of the Residue of (carbon-14)-Dicloran (Botran Technical) in Lactating Goats: Final Report: Lab Project Number: HWI 6564-102: 6564-102. Unpublished study prepared by Hazleton Wisconsin, Inc. 121 p.
44099301	Jacobson, S. (1996) Independent Laboratory Confirmation of Analytical Method R-450.2 for Residues of DCNA in Various Crops: Final Report: Lab Project Number: 95036. Unpublished study prepared by Compliance Services International. 107 p.
44215401	Coody, P. (1997) Small Scale Prospective Ground Water Study for Botran 75W (DCNA) Applied to Head Lettuce in Monterey County, California: First Quarterly Report: Lab Project Number: 961: 1939. Unpublished study prepared by PTRL East, Inc. and Weber, Hayes & Assoc. 124 p.
44233803	Wilcox, S.; Barton, S. (1996) Dicloran Preliminary Reproduction Toxicity Study in Rats: Lab Project Number: 11522: 491509. Unpublished study prepared by Inveresk Research International. 45 p.
44237801	O'Neal, S. (1997) Metabolic Fate and Distribution of (carbon 14)-Dicloran in Potatoes: (Final Report): Lab Project Number: 857: 1947. Unpublished study prepared by PTRL East, Inc. 154 p.
44245201	O'Neal, S. (1997) Metabolic Fate and Distribution of (carbon 14)-Dicloran in Lettuce: (Final Report): Lab Project Number: 856: 1949. Unpublished study prepared by PTRL East, Inc. 134 p.
44258801	Kemman, R. (1997) Determination of the Frozen Stability of DCNA in Lettuce and Carrot Roots: Final Report: Lab Project Number: 95033: 66009. Unpublished study prepared by Compliance Services International. 129 p.
44348201	O'Neal, S. (1997) A Confined Rotational Crop Study with (carbon 14)-Dicloran: (Final Report): Lab Project Number: 858: 1960. Unpublished study prepared by PTRL East, Inc. 253 p.
44350101	Coody, P. (1997) Small Scale Prospective Ground Water Study for Botran 75W (DCNA) Applied to Head Lettuce in Monterey County, California: Second Quarterly Report: Lab Project Number: 961: 1939. Unpublished study prepared by PTRL East, Inc. and Weber, Hayes & Associates. 22 p.
44414101	Wilcox, S.; Barton, S. (1997) Dicloran: Two Generation Reproduction Study in Rats:

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	Lab Project Number: 491514: 14271. Unpublished study prepared by Inveresk Research. 363 p.
44414201	Kliskey, E. (1997) Determination of the Dissipation of Residues of 2,6-Dichloro-4-nitroaniline (Dicloran) and its Metabolites in a California Bare Ground Field Treated with Botran: Lab Project Number: GOWN-9321: F94084-207: GOWN-9321-CA1. Unpublished study prepared by Compliance Services International. 418 p.
44533001	Howard, J. (1998) Small Scale Prospective Ground Water Study for Botran 75W (DCNA) Applied to Head Lettuce in Monterey County, California: Third Quarterly Report: Lab Project Number: 961: 2000. Unpublished study prepared by PTRL East, Inc. and Weber, Hayes & Assoc. 50 p.
44694301	Howard, J. (1998) Small Scale Prospective Ground Water Study for BOTRAN 75 W (DCNA) Applied to Head Lettuce in Monterey County, California: Fourth Quarterly Report: Lab Project Number: 961: 2020. Unpublished study prepared by PTRL East, Inc. and Weber, Hayes, and Associates. 97 p.
44474101	Wnorowski, G. (1997) Acute Oral Toxicity Limit Test (in Rats): (Hospital Broad Band Disinfectant): Lab Project Number: 5382: P320. Unpublished study prepared by Product Safety Labs. 15 p.
44842101	Howard, J. (1999) Small Scale Prospective Ground Water Study for Botran 75W (DCNA) Applied to Head Lettuce in Monterey County, California: Lab Project Number: 961: 2041. Unpublished study prepared by PTRL East, Inc. and Weber, Hayes & Associates. 217 p.
45062001	Howell, C. (2000) Dissipation of Dislodgeable Foliar Dichloran (DCNA) Residues from Snap Beans Following 5 Applications of Botran 75W: Lab Project Number: 99793: 45433. Unpublished study prepared by ABC Labs. 140 p. {OPPTS 875.2100}
45159801	Mickelson, K. (2000) Dicloran: Field Rotational Crop Study: Lab Project Number: AA980602: 97-0065. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Laboratories. 355 p. {OPPTS 860.1900}
45237401	Howard, J.; White, J. (2000) Small Scale Prospective Ground Water Study for BOTRAN 75W (DCNA) Applied to Head Lettuce in Monterey County, California: Final Report: Lab Project Number: 961: 2103: 2000. Unpublished study prepared by PTRL East, Inc. and Weber, Hayes & Associates. 806 p.
45265001	Wartanessian, S. (1996) Magnitude of Residues in/on Fresh Tomatoes after Post-Harvest Treatment with Dicloran: Lab Project Number: DICLORAN TOM95. Unpublished study prepared by Elf Atochem North America, Inc. 20 p.
45333301	Hawk, R. (2001) Anaerobic Aquatic Metabolism of (carbon 14)-Dicloran: Addendum 1: Lab Project Number: XBL94111: RPT00235. Unpublished study prepared by Xenobiotic Labs., Inc. 23 p.
45397001	Jaglan, P.; Arnold, T. (1985) Dicloran (DCNA): Photolysis of (Carbon-14)-Dicloran from Aqueous Solutions: Preliminary Study. Lab Project Number: 218-9760-85-005. Unpublished study prepared by The Upjohn Company. 31 p.
45492601	Teeter, D. (1998) Validation of Methods for the Determination of Dicloran Using Eggs and Tissues and Milk From Laying Hen and Lactating Goat Metabolism Studies: Final Report: Lab Project Number: 6564-113. Unpublished study prepared by Covance Laboratories. 61 p. {OPPTS 860.1340}
45525801	Hawk, R.; Winkler, V. (2001) Dicloran (DCNA) Environmental Fate Studies: Lab

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	Project Number: GEC101. Unpublished study prepared by Gowan Company. 288 p.
45575001	Hawk, R.; Winkler, V. (2001) Dicloran (DCNA) Environmental Fate Studies: Lab Project Number: GEC101. Unpublished study prepared by Gowan Company. 446 p.
45610801	Killeen, J. (2002) A 52-Week Oral Toxicity Study in Dogs with Dicloran: Lab Project Number: 012260-1. Unpublished study prepared by Ricerca, LLC. 329 p.
46216001	Volkl, S. (2003) (Carbon 14)-Dicloran: Route and Rate of Degradation in Aerobic Aquatic Systems. Project Number: 843085, 714/001. Unpublished study prepared by RCC Umweltchemie Ag and SCC Scientific Consulting Company. 171 p.
46218900	Gowan Company (2004) Submission of Toxicity Data in Support of the Reregistration of Dicloran. Transmittal of 1 Study.
46218901	Frey, L.; Martin, K.; Beavers, J.; et. al. (2003) Dicloran: A Reproduction Study with the Northern Bobwhite: Final Report. Project Number: 813/001, 90000308, 555/104. Unpublished study prepared by Wildlife International, Ltd. 190 p.
46360701	Ramesh, E. (2004) Combined Chronic Toxicity and Carcinogenicity Study with Dicloran in Wistar Rats. Project Number: 3080/00, 1835, 1807. Unpublished study prepared by Rallis Research Centre, Rallis India. 1381 p.
46360702	Ramesh, E. (2001) Dicloran: 90- Day Dietary Dose Range Finding Study in Wistar Rats. Project Number: 3080/01. Unpublished study prepared by Rallis Research Centre, Rallis India. 92 p.
46447501	Gerspach, R. (2003) Dicloran: Prenatal Developmental Toxicity Study in the Rat. Project Number: 843083. Unpublished study prepared by RCC Ltd. 318 p.
46657101	Volkl, S. (2003) (Carbon 14)-Dicloran: Route and Rate of Degradation in Aerobic Aquatic Systems. Project Number: 90000270, 714/001, 843085. Unpublished study prepared by RCC Umweltchemie Ag. 171 p.
46657102	Peither, A. (2003) Sublethal Toxic Effects of Dicloran to Rainbow Trout (Oncorhynchus mykiss) in a Fish Juvenile Growth Test Over 28 Days. Project Number: 843088, 826/002, 90000297. Unpublished study prepared by RCC Umweltchemie Ag. 69 p.
46657103	Peither, A. (2003) Influence of Dicloran on Survival and Reproduction of Daphnia magna in a Semi-Static Test Over Three Weeks. Project Number: 843091, 90000290, 827/001. Unpublished study prepared by RCC Umweltchemie Ag. 60 p.
46657104	Schmidt, T. (2003) Effects of Dicloran on the Development of Sediment-Dwelling Larvae of Chironomus riparius in a Water-Sediment System. Project Number: 90000305, 846095, 843096. Unpublished study prepared by RCC Umweltchemie Ag. 116 p.
46657105	Seyfried, B. (2003) Toxicity of Dicloran to Scenedesmus subspicatus in a 72-Hour Algal Growth Inhibition Test. Project Number: 90000295, 823/001, 843093. Unpublished study prepared by RCC Umweltchemie Ag. 62 p.

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Appendix E.
Generic Data Call-In

The Generic Data Call-In will be posted at a later date. See Chapter V of the DCNA
RED for a list of studies required.

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Appendix F.
Product Specific Data Call-In

The product specific Data Call-In will be posted at a later date.

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Appendix G.
EPA's Batching of DCNA Products for Meeting Acute Toxicity Data Requirements for Reregistration

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product

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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.

Ten products were found which contain DCNA as the active ingredient. These products have been placed in one batch and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

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

Batch 1	EPA Reg. No.	Percent Active Ingredient
	10163-189	75.0
	10163-207	75.0

No Batch	EPA Reg. No.	Percent Active Ingredient
	2935-529	6.0
	10163-188	6.0
	10163-195	95.0
	10163-221	43.0
	10163-226	46.0
	10163-239	65.0
	10951-13	6.0
	10951-14	Dicloran: 6.0 Sulfur: 25.0

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Appendix H.
List of Registrants Sent This Data Call-In

A list of registrants sent this Data Call-In will be posted at a later date.

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Appendix I.
List of Available Related Documents and Electronically Available Forms

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

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

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

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf

8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

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

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program – Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied Through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires Acrobat reader.)

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Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_NoticesPesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' website.

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

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

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

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

1. Date of receipt;
2. EPA identifying number; and
3. Product Manager assignment.

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

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

Documents Associated with this RED

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

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.

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i. DP Barcode D265094, T. Bloem, 4/20/00.

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