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Reregistration Eligibility Decision for Chloroneb

Reregistration Eligibility Decision (RED) Document for Chloroneb

List A

Case No. 0007

Approved by: _____ Date:_____

Debra Edwards, Ph. D. Month Day, 2005
Director
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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
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
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
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
GLN	Guideline Number
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
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
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
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA) has concluded its reregistration eligibility decision for chloroneb and determined that the chemical is eligible for reregistration provided that: (1) current data gaps and additional data needs are addressed; (2) the risk mitigation measures outlined in this document are adopted; and (3) label amendments are made to implement these measures. EPA has also reassessed tolerances for chloroneb. The 24 tolerances for chloroneb are now considered reassessed as safe under section 408(q) of FFDCA, as amended by FQPA.

EPA has completed its review of the public comments on the chloroneb risk assessments and is issuing its risk management decision. The risk assessments are based on review of the available data base supporting the use patterns of currently registered products and additional information received. After considering the risks identified in the risk assessment, comments, and mitigation suggestions from interested parties, EPA developed its risk management decision for uses of chloroneb that pose risks of concern.

Chloroneb (1,4-dichloro-2,5-dimethoxybenzene) is a fungicide currently registered for use on a wide variety of food crops but is primarily used for pre-plant cottonseed treatment as well as on commercial turf and ornamentals. The markets for chloroneb seed treatment uses include: sugar beets, soybeans, cotton, and beans. Treated cottonseed are used in the cotton growing states of CA, AZ, MS, LA, AR, TX and KS with lower use in AL, GA, SC, TN and NC. Uses on turf are primarily in midwestern and northeastern states as well as FL.

Confirmation that the seed treatment uses of chloroneb constitute food uses requiring tolerances (food/feed and possibly meat/milk) and reevaluation of the limited chloroneb database has led to conclusions that numerous additional toxicology and residue chemistry data are now required to support the reregistration of chloroneb. The toxicology and residue chemistry databases are not complete due primarily to unacceptable older or missing studies.

The key data that are required include: (1) the 2-generation reproduction data in the rat; (2) oncogenicity data in the mouse; and (3) combined chronic toxicity/oncogenicity data in the rat. The Agency concluded that the toxicology data base for chloroneb is not complete, since an acceptable 2-generation reproduction study is not available and therefore an FQPA 10X database uncertainty factor has been retained. In addition, the Agency is requiring other studies for the reregistration of chloroneb.

Overall Risk Summary

No acute dietary assessment was performed since an endpoint attributable to a single exposure was not identified from the available database. Chronic (non-cancer) risks from combined food and water are below the Agency's level of concern and the Agency concluded that chloroneb is unlikely to pose a dietary cancer risk. There is a potential risk from postapplication exposure (dermal and

incidental oral) in residential settings, such as recreational areas, golf courses, and home lawns resulting from entering areas previously treated with chloroneb. There is also a potential risk from occupational exposure from the application of chloroneb on both food and non-food use sites resulting from handling chloroneb products (i.e., mixer/loaders and applicators) and for occupational postapplication exposure resulting from entering areas previously treated with chloroneb. For ecological risks, there are exceedences of the level of concern (LOC) for endangered species, or no data to dismiss the concern for endangered species, in the following taxa: avian, mammal, freshwater fish and invertebrates, and estuarine/marine organisms. For avian and freshwater organisms, the risk quotients exceeded the endangered species acute LOC, and no chronic data are available. For mammals and estuarine/marine organisms, no relevant acute or chronic data are available to dismiss the concern for endangered species.

Risk Mitigation

To mitigate residential and occupational risks to chloroneb and to reduce potential exposures to wildlife, the registrant has agreed to:

- voluntarily cancel the use of chloroneb on residential lawns and turf, as well as on lawns and turf at parks and schools;

- amend its label to remove ornamentals, all other turf, bedding plants, ferns, and on-farm seed treatment from its label pending the Agency receipt, review, and acceptance of a 21-day dermal toxicology study and reevaluation of risk; and,

- voluntarily amend labeling for turf uses as follows, if the revised risk assessment based on the dermal toxicity study indicates (see above) acceptable risks:

    - restrict use on turf to golf course tees, greens, collars, aprons, and spot treatment of fairways, as well as professional athletic turf (football, baseball fields, etc.)

    - limit the number of applications on golf courses to 6 per year; 4 applications at 7 lb ai/A and 2 applications at 16 lb ai/A

    - limit maximum use per year on golf courses to 60 lb ai/acre/year

    - require a minimum retreatment interval of 14 days for golf course tees, greens, and aprons, and professional athletic fields;

- replace the wettable powder formulation with the use of water soluble packaging for commercial seed treatment, and require a closed loading system when loading/applying liquid for commercial seed treatment.

Next Steps

The Agency is issuing this Reregistration Eligibility Decision (RED) document for chloroneb as announced in a Notice of Availability published in the ***Federal Register***. In the future, EPA will issue a generic Data Call-In (DCI) for additional data necessary to confirm the conclusions of this RED for the active ingredient chloroneb. EPA will also issue a product specific DCI for data necessary to complete product reregistration for products containing chloroneb.

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 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The Act calls for the development and submission of data to support to support the reregistration of an active ingredient, as well as a review of all submitted data to the U.S. Environmental Protection Agency (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 and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996 by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. 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 the 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://epa.gov/pesticides/cumulative/.

Unlike other pesticides for which EPA has considered cumulative risk based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for chloroneb. The Agency has found no information indicating chloroneb shares a common mechanism of toxicity with other substances. Chloroneb does not appear to produce a toxic metabolite produced by other

substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA is not assuming that chloroneb shares a common mechanism of toxicity with other compounds. In the future, if additional information suggests chloroneb shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary.

This document presents EPA's revised human health and ecological risk assessments and its progress toward tolerance reassessment, and the reregistration eligibility decision for chloroneb. 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. Finally, the Appendices (section VI) list related information, and supporting documents. The preliminary and revised risk assessments for chloroneb are available in the Public Docket, under docket number OPP-2004-0369 and on the Agency's web page, http://www.epa.gov/edockets.

II. Chemical Overview

Chloroneb (1,4-dichloro-2,5-dimethoxybenzene) is a fungicide currently registered for use on a wide variety of food crops but is primarily used for pre-plant cottonseed treatment as well as on commercial turf and ornamentals. The markets for chloroneb seed treatment uses include: sugar beets, soybeans, cotton, and beans. Treated cottonseed are used in the cotton growing states of CA, AZ, MS, LA, AR, TX and KS with lower use in AL, GA, SC, TN and NC. Turf uses are primarily in midwestern and northeastern states as well as FL for use on golf courses.

Tables 1 and 2 provide an overview of chloroneb's structure and properties.

Table 1. Chloroneb Nomenclature.

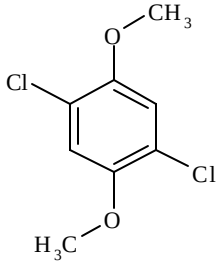
Chemical structure	
Common name	Chloroneb
Molecular Formula	$C_8H_8Cl_2O_2$
Molecular Weight	207.06

Table 1. Chloroneb Nomenclature.	
IUPAC name	1,4-dichloro-2,5-dimethoxybenzene
CAS name	1,4-dichloro-2,5-dimethoxybenzene
CAS #	2675-77-6
PC Code	027301

Table 2. Physicochemical Properties of Chloroneb.	
Parameter	Value
Melting point/range	128-130 C
pH	N/A; chloroneb is not dispersible in water
Density	0.8814 g/mL ± 2.11% (temperature not specified)
Water solubility, at 20 °C	2.09×10^{-2} g/L
Solvent solubility, at 20 °C	Chloroform 284 g/L Benzene 189 g/L Acetone 140 g/L Ethanol 15.9 g/L Methanol 15.5 g/L Petroleum ether 14.6 g/L
Vapor pressure, at 25 °C	3×10^{-3} mm Hg (PAI)
Dissociation constant, pK_a	N/A; chloroneb is insoluble in aqueous solutions
Octanol/water partition coefficient, $Log(K_{OW})$, at 24.5 °C	2.99
UV/visible absorption	No Data Available

Formulations

Chloroneb products include flowable concentrate, granular, and wettable powder.

Application Rate

- The maximum rates for seed treatment uses are: 3.0 oz ai/hundred weight of seed (cwt) (or 0.19 lb ai/per cwt) for beans, lupine, and soybeans; 3.9 oz ai/cwt of seed (or 2.4 lb. ai/cwt) for sugar beets; and 7.8 oz ai/cwt of seed (or 0.49 lb ai/cwt) for cottonseed. The maximum foliar use rates on turf grasses are 15.9 lb ai/A for the wettable powder and 16.2 lb ai/A for the granular formulations. Chloroneb formulated as wettable powder, and flowable concentrate is registered for use on ornamental plants at a maximum foliar use rate of 3.9 lb ai/A. Chloroneb is generally applied as a single application, but may be used as a follow-up application, depending on factors such as disease pressure (outbreak) and weather.

Methods of Application

- Chloroneb can be applied as a seed treatment, foliar spray, chemigation, ground spray, drip, and soil drench.

Use Summary

As Table 3 illustrates below, available data do not suggest chloroneb is a widely used pesticide.

Table 3: Estimated Usage of Chloroneb

Crop	Percent Crop Treated	Basis
Cotton[a]	2%	CA treated 1-2% of cotton in 2002 and less in 2001. No usage on cotton crop indicated in USDA/NASS 1997 - 2001 & 2003 nor in EPA propriety data 1995 - 2003. (CA grows 12% of US cotton.)
Beans[a]	5%	CA treated 5% of dry beans in 2002. No usage on any bean crop indicated in USDA/NASS 1998, 2000 & 2002 nor in EPA proprietary data 1995 - 2003. (CA grows 6% of US dry beans.)
Soybeans	<1%[b]	No usage on soybean crop indicated in USDA/NASS 1998-2003 nor in EPA proprietary data 1995-2003. No usage indicated on soybeans post-harvest in USDA/NASS 1999.
Sugarbeets	<1%[b]	No usage on sugarbeet crop indicated in EPA proprietary data 1995-2003.
Nursery & Floriculture	<1%	Less than 3,000 lbs used with an application rate of 2 lbs a.i. per acre per year.
Golf Courses	<1%	Based on EPA proprietary data 1998- 2001.

[a] Usage information only reflects use in California.

[b] Databases listed did not detect use on the crop.

Tolerances

- Currently there are 24 chloroneb tolerances.

Technical Registrant

- Kincaid Enterprises, Inc

III. Summary of Chloroneb Risk Assessment

The following is a summary of EPA's health and ecological risk findings and conclusions for chloroneb, as presented fully in the documents: "Chloroneb HED Chapter PC Code 027301. DP

Barcode D297697" (12/30/2004); "Chloroneb: Characterization of Potential Carcinogenic Risk from Dietary Exposure PC Code: 027301: DP Barcode D319995" (09/21/2005); "Environmental Fate and Effects Division Risk Assessment for the Reregistration Eligibility Document for Chloroneb DP Barcode D310822." (12/31/2004); "Tier 1 Drinking Water Exposure Assessment for Chloroneb (11/15/2004); and "Phase 4: Risk Mitigation for Occupational Exposure to Chloroneb in Commercial Seed Treatment Scenarios." (9/26/2005); and "Revised Occupational Postapplication Exposure and Risk Assessment for Chloroneb." (9/29/2005).

The purpose of this section is to summarize 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 documents are not included in this document they are available in the public docket (docket # OPP-2004-0369) and the Agency's website at: http://www.epa.gov/pesticides/reregistration/status.htm.

A. Human Health Risk Assessment

The Agency has conducted a human health risk assessment for chloroneb for the purposes of making a reregistration decision. Although there are several studies missing from the database, the Agency evaluated the toxicology, product and residue chemistry, and occupational/residential exposure studies submitted for chloroneb and determined that the data are adequate to support a reregistration decision. More in depth details of the toxicity, product and residue chemistry, and occupational/residential studies used to develop the risk assessments and to support the guidelines are provided in the human health risk assessment and separate disciplinary chapters associated with this document. These documents are available in the electronic docket. A summary of the human health risk assessment findings and conclusions is provided in the following subsections below.

1. Hazard Profile

The toxicology database is not complete due primarily to unacceptable older or missing studies. Data considered key to the chloroneb risk assessment which are now required are the: 2-generation reproduction data in the rat; oncogenicity data in the mouse; and combined chronic toxicity/oncogenicity data in the rat. A special hazard based FQPA safety factor is not required since there are no residual uncertainties for prenatal toxicity, but an FQPA database uncertainty factor (UF) of 10X is required due to the lack of an acceptable 2-generation reproductive toxicity study.

There are no acceptable oncogenicity studies with which to assess the carcinogenic potential of chloroneb. In a non-guideline rat carcinogenicity study, no compound-related effects were observed in the tumor results; this study was deemed unacceptable due to several significant flaws. However, several mutagenicity studies indicate that chloroneb is not a mutagen. Chloroneb did test positive for chromosome damage in one mammalian cell line, but negative in another. Chloroneb did not cause unscheduled DNA synthesis in rat hepatocyte cultures. Together, the data suggest that chloroneb does

not react directly with DNA and if it were determined to be a carcinogen, there is a strong possibility it would exhibit a threshold response. If it did exhibit a threshold response, the existing methodology for estimating non-cancer risks which utilizes a NOAEL from a chronic (2-year) dog study and a 1,000 fold composite uncertainty factor would be adequately protective for cancer. To confirm this assumption, both rat and mouse carcinogenicity studies will be required as a follow-up to this RED.

Acute toxicity studies (Table 4) with the formulated products (e.g., wettable powder) indicate low toxicity via the oral, dermal, and inhalation routes (Category IV), but chloroneb is a dermal sensitizer.

Table 4. Acute Toxicity Profile - Test Substance

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral -rat; Demosan 88% chloroneb	00032544	LD_{50} > 5,000 mg/kg	IV
870.1200	Acute dermal -rabbit; chloroneb 75% WP	00093893	LD_{50} > 5,000 mg/kg	IV
870.1300	Acute inhalation -rat; chloroneb 65% WP	00004982	LC_{50} = 25.2 mg/L	IV
870.2400	Acute eye irritation -rabbit; chloroneb 65% WP	00004983	conjunctivitis	III
870.2500	Acute dermal irritation -rabbit; Nu Flo ND chloroneb 30%	00032544	slightly irritating	IV
870.2600	Skin sensitization -guinea pig; chloroneb 35.5% a.i.	00063019	sensitizer	

The toxicological doses and endpoints for chloroneb for use in the human risk assessment are found in Table 5.

Table 5. Summary of Toxicological Doses and Endpoints for Chloroneb for Use in Human Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (All populations)	NOAEL= 12.5 mg/kg/day UF = 1000 **Chronic RfD** = 0.013 mg/kg/day	FQPA SF = 1 **cPAD** = chronic RfD / FQPA SF = 0.013 mg/kg/day	2-year dog feeding study LOAEL = 62.5 mg/kg/day based on body weight loss, increased absolute and relative liver weight, increased alanine aminotransferase (ALT) and/or alkaline phosphates, hepatocyte pigmentation, moderate thyroid activity

Table 5. Summary of Toxicological Doses and Endpoints for Chloroneb for Use in Human Risk Assessments			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Short- and Intermediate-Term Incidental Oral (1-30 days and 1-6 months)	NOAEL= 25 mg/kg/day	**Residential** LOC for MOE = 1000 **Occupational** = Not applicable (NA)	90-day rat feeding study LOAEL = 250 mg/kg/day based on increased urinary glucose in both sexes, increased urinary epithelial cells in males and urinary leukocytes in females, liver cell hypertrophy, and renal tubular degeneration
Short- and Intermediate-Term Dermal (1 to 30 days, and 1-6 months)	Oral study NOAEL= 25 mg/kg/day (dermal absorption rate is assumed to be 100%; default assumption)	**Residential** LOC for MOE =1000 **Occupational** LOC for MOE =100	90-day rat feeding study LOAEL = 250 mg/kg/day based on increased urinary glucose in both sexes, increased urinary epithelial cells in males and urinary leukocytes in females, liver cell hypertrophy, and renal tubular degeneration
Short- and Intermediate-Term Inhalation (1 to 30 days and 1-6 months)	Oral study NOAEL= 25 mg/kg/day (dermal absorption rate is assumed to be 100%; default assumption)	**Residential** LOC for MOE = NA **Occupational** LOC for MOE = 100	90-day rat feeding study LOAEL = 250 mg/kg/day based on increased urinary glucose in both sexes, increased urinary epithelial cells in males and urinary leukocytes in females, liver cell hypertrophy, and renal tubular degeneration

2. Dietary Exposure and Risk from Food and Water

a. Acute Dietary (Food and Water)

An acute reference dose was not determined because an appropriate quantitative estimate of hazard (i.e., an adverse effect attributable to a single dose) was not identified from the toxicological database to which an acute exposure estimate could be compared.

b. Chronic Dietary (Food and Water)

A risk estimate that is less than 100% of the chronic PAD (cPAD) (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) is not of concern to the Agency. A Tier 1 chronic (non-cancer) dietary risk assessment was conducted using the Lifeline ^{TM} Model Version 2.0 with food consumption data from the United States Department of Agriculture's (USDA) Continuing Surveys of Food intakes by the Individuals (CSFII) from 1994-1996 and 1998.

Drinking water contribution to the dietary exposure was incorporated into Lifeline as a point estimate. Drinking water estimation methods are summarized below. For a more complete explanation of the addition of water in the dietary analysis, please see the health effects risk assessment and the drinking water memorandum.

The Uncertainty Factor is 1000, which includes 10X for inter-species extrapolation, 10X for intra-species variability, and a 10X FQPA database uncertainty factor, due to data gaps. The chronic PAD equals 0.013 mg/kg/day. The most highly exposed population subgroup was all infants <1 year of age at 65% cPAD (food and water), which is below the Agency's level of concern (Table 6).

Table 6. Summary of Chronic (non-cancer) Dietary Exposure and Risk for Chloroneb

Population Subgroup	cPAD, mg/kg/day	Food Only		Food + Water	
		Exposure, mg/kg/day	% cPAD	Exposure, mg/kg/day	% cPAD
General U.S. Population	0.013	0.001151	9	0.002159	22
All Infants (< 1 yr)		0.001789	14	0.005808	65
Children 1-2 yrs		0.003510	27	0.005595	54
Children 3-5 yrs		0.002916	22	0.004718	46
Children 6-12 yrs		0.001883	14	0.002972	29
Youth 13-19 yrs		0.001091	8	0.001848	18
Adults 20-49 yrs		0.000937	7	0.001833	19
Adults 50+ yrs		0.000902	7	0.001828	19
Females 13-49 yrs		0.001070	8	0.002049	21

c. Drinking Water Estimates

Typically, EPA evaluates the potential for human exposure to pesticides in drinking water through an assessment of available surface water and groundwater monitoring data and modeling. Drinking water exposure to pesticides can occur through surface and/or ground water contamination. EPA considers acute (one day), chronic (lifetime), and cancer (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is carried out in tiers of further refinement, but is designed to provide a high-end estimate of exposure.

There were no monitoring data for chloroneb in water available to the Agency. The drinking water estimated concentrations (DWECs) for human health risk assessment are based on ornamental turf use, assume an unrestricted use pattern, and include total toxic (non-volatile) residues (Table 7). A site in Florida was chosen, as this site is expected to be the most vulnerable.

The ornamental spring and fall turf use patterns were used in the aquatic modeling. They were chosen over the late fall application pattern even thought that pattern has a much higher single application rate (16.2 lb a.i./acre), because the time period that encompasses "late fall" (approximately six weeks) is

shorter than the time period that could be considered "spring " and "fall" (approximately six months). Therefore, because the labels for these uses do not specify maximum number of applications or application intervals, there is the potential for more active ingredient to be applied using the spring and fall use patterns.

Table 7. Summary of Estimated Surface and Ground Water Concentrations for Chloroneb.

Exposure Duration	Chloroneb	
	Surface Water Conc., ppb[a]	Ground Water Conc., ppb[b]
Acute	2140	69.1
Chronic (non-cancer)	118	69.1

[a] From the Tier 2 PRZM-EXAMS - Index Reservoir model. Input parameters are based on golf course and ornamental turf use (8.85 lb ai/A/application, 20 applications/season, 3-day retreatment interval) and include total toxic (non-volatile) residues.

[b] From the SCI-GROW model. Input parameters are based on ornamental turf use (8.85 lb ai/A/application, 20 applications/season, 3-day retreatment interval) and include total toxic (non-volatile) residues.

It is highly likely that this conservative set of DWECs exceed the values that occur in the environment. The predicted values are based on essentially unrestricted label use patterns (twenty applications at 8.85 lb ai/A spaced at 3-day intervals) and the very limited environmental fate data set available for chloroneb. Such an application practice is not likely to be used, but would not be prohibited by the current label.

3. Residential Exposure and Risk

Residential risk assessments were conducted for postapplication (non-occupational) scenarios (dermal and incidental oral) using standard exposure inputs and assumptions in the absence of chemical-specific data, including 100% dermal absorption for dermal exposures, and are based on the maximum registered use rate for chloroneb **(**15.9 lb ai/A spray treatment on turf grass). Exposure duration is considered short-term (1-30 days); hence, the short-/intermediate-term endpoint was used for all risk assessments. Registered use of chloroneb on turf may result in individuals of varying ages potentially being exposed as a result of activities in areas that have been treated. Chloroneb products are only professionally applied in the residential settings; therefore residential handler exposure is not expected.

a. Residential Postapplication Exposure and Risk

Of the residential (non-occupational) postapplication scenarios evaluated, all had MOEs of concern (< 1000) (Table 8). The target Margin of Exposure (MOE) is 1000 for residential assessments. This is based on 10X for intraspecies extrapolation, 10X interspecies variation, and an additional 10X FQPA data base uncertainty factor due to data gaps.

Table 8. Residential (Non-Occupational) Risk from Treated Turf					
Population Subgroup	Scenario (Transfer Coefficient, cm^2/hr)	Route	MOE		Total MOE[1]
			(HED LOC for MOE is 1000)		
Adult	High Contact Activities (HCA) (14500)	Dermal	6.8		NA
	Golfer (500)	Dermal	98		
Child	High Contact Activities (HCA) (5200)	Dermal	4		3.8
	Hand-to-Mouth (HTM)	Oral	110	87	
	Object-to-Mouth (OTM)	Oral	420		
	Soil Ingestion (SI)	Oral	31000		

[1]Total MOE = $1 / (1/MOE_{HCA} + 1/MOE_{HTM} + 1/MOE_{OTM} + 1/MOE_{SI})$

4. Aggregate Exposure and Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water pathways) as well as exposures from non-occupational sources (e.g., residential uses). Potential exposures from food, drinking water, and residential scenarios were considered, and aggregated for chloroneb. The pathways for adults lead to exposure via the oral (dietary) and dermal (residential) routes. The pathways for children lead to exposure via the oral (dietary) and, dermal and incidental oral (residential) routes.

Acute exposures were not considered because an appropriate quantitative estimate of hazard (i.e., an adverse effect attributable to a single dose) was not identified from the toxicological database to which an acute exposure estimate could be compared.

There is potential short-term exposure to chloroneb via the dietary and residential pathways. The aggregate risks from residential exposure alone (excluding dietary exposure), all had MOEs of concern (<1000) (see residential risk section for MOEs).

Because no long-term residential exposure scenarios are expected, the chronic aggregate assessment considered only food and drinking water exposures. The chronic dietary (food + water) risk assessment was conducted using total toxic residue estimates, an additional 10X FQPA database uncertainty factor for the lack of certain toxicology data, 100% crop treated, and maximum theoretical concentration factors for cottonseed oil and soybean oil. The chronic risk estimate was below the Agency's level of concern for the U.S. General population and all subgroups. Dietary exposures from

food and water combined ranged from 18% to 65% (infants <1 year of age) of the chronic Population Adjusted Dose (cPAD).

5. Occupational Exposure and Risk

Workers can be exposed by mixing, loading, or applying (handlers) chloroneb or by entering a previously treated site (postapplication). Worker risk is also measured as a MOE, which determines how close the occupational exposure comes to a NOAEL. The Agency initially calculates a "baseline assessment" which is the handler's risk using the least amount of protective measures. For individuals involved in applications, this assessment normally accounts for an individual's normal work clothing (e.g., long sleeve shirt and long pants), no gloves, and no respirator. If there is a concern at this level, the Agency considers the use of protective measures (e.g., personal protective equipment and engineering controls) to lower the risk. Personal protective equipment (PPE) can include an additional layer of clothing, chemically-resistant gloves, and a respirator. Common examples of engineering controls include: enclosed tractor cabs, closed loading systems, and water-soluble packaging.

Occupational risk assessments were conducted for handler and postapplication exposure scenarios. Assessments were conducted using standard exposure values and assumptions in the absence of chemical-specific data, including 100% dermal absorption, and are based on the maximum registered use rates for chloroneb. The occupational level of concern (LOC) is based on the conventional uncertainty factor of 10X for intraspecies extrapolation and 10X for interspecies variation. Therefore, MOEs >100 are below the Agency level of concern.

Occupational handlers may be exposed by the dermal route and by the inhalation route during mixing, loading and application of chloroneb for both short-and intermediate-term durations.

A number of occupational handler exposure scenarios, even after the inclusion of the highest possible PPE level (not including engineering controls), had MOEs of concern (<100). These scenarios included:

- all mixer/loader/application scenarios for turf/woody ornamentals/bedding plants/ferns
- mixing/loading wettable powder for groundboom application on turf
- all loader/applicator scenarios for the use of wettable powder (WP) formulations in commercial seed treatments
- loading/applying liquid and multiple activities for commercial soybean seed treatment
- all on-farm seed treatment scenarios except sugar beets.

The MOEs of concern ranged from 8.9 - 97 and are shown in Table 9.

Table 9. Short-/Intermediate-Term Occupational Handler Risk Estimates for Chloroneb

Exposure Scenario [PHED Unit Exposures unless otherwise noted]	Daily Area Treated[1]	Crop/Target	Application Rate[2]	Combined MOE[3]	Mitigation Level[4]
Mixer/Loader					
Mixing/Loading Wettable Powder for Groundboom application	40	Turf	15.9	15	PPE - Baseline+Gloves/80% R
Mixer/Loader/Applicators & Loader/Applicators					
M/L/A Wettable Powder with a Low Pressure Handwand Sprayer	40	Turf	0.07312	68	PPE - Baseline+Gloves/80% R
		Woody Ornamentals, Bedding Plants, and Ferns	0.078	63	PPE - Baseline+Gloves/80% R
M/L/A Wettable Powder with a Handgun Sprayer (ORETF data)	5	Turf	15.9	28	PPE - Baseline+Gloves/80% R
M/L/A Wettable Powder with a High Pressure Handwand	1000	Woody Ornamentals, Bedding Plants, and Ferns	0.078	8.9	PPE - Baseline+Gloves/80% R
M/L/A Wettable Powder in Water Soluble Packets with a Handgun Sprayer (ORETF data)	5	Turf	15.9	34	PPE - Baseline+Gloves/80% R
L/A granules with a Push-type Spreader (ORETF data)	5	Turf	16.2	95	PPE - Baseline+Gloves/NR
				97	PPE - Baseline+Gloves/80% R
Loader/Applicator					

Table 9. Short-/Intermediate-Term Occupational Handler Risk Estimates for Chloroneb					
Exposure Scenario [PHED Unit Exposures unless otherwise noted]	**Daily Area Treated[1]**	**Crop/Target**	**Application Rate[2]**	**Combined MOE[3]**	**Mitigation Level[4]**
Loading Wettable Powder for Commercial Seed Treatment (PHED data)	160000	Cotton	0.004875	16	PPE - Double Layer+Gloves/80% R
	718000	Soybeans	0.001875	9.4	PPE - Double Layer+Gloves/80% R
	194000	Beans, other	0.001875	35	PPE - Double Layer+Gloves/80% R
	88000	Sugar Beets	0.002438	59	PPE - Double Layer+Gloves/80% R
Loading/Applying Liquid for Commercial Seed Treatment	718000	Soybeans	0.001875	72	PPE - Double Layer+Gloves/80% R
Multiple Activities					
Multiple Activities for Commercial Seed Treatment	718000	Soybeans	0.001875	61	PPE - Double Layer+Gloves/80% R
On-Farm Seed Treatment					
On-Farm Seed Treatment using Wettable Powder or Liquid formulations	3600	Cotton	0.004875	16	PPE - Double Layer+Gloves/80% R
	12000	Soybeans	0.001875	12	PPE - Double Layer+Gloves/80% R
	8000	Beans, other	0.001875	19	PPE - Double Layer+Gloves/80% R

[1]Amount treated is expressed in acres/day for all scenarios, except M/L/A Wettable Powder with a Low Pressure Handwand Sprayer, M/L/A Wettable Powder with a High Pressure Handwand, and M/L/A Wettable Powder in Water Soluble Packets with a Handgun Sprayer which are expressed in gallons/day, and seed treatment is expressed as lbs seed/day.

[2]Application rates are expressed as lbs ai/acre for all scenarios except M/L/A Wettable Powder with a Low Pressure Handwand Sprayer, M/L/A Wettable Powder with a High Pressure Handwand, and M/L/A Wettable Powder in Water Soluble Packets with a Handgun Sprayer which are expressed in lb ai/gallon, and seed treatment are expressed as lb ai/lb seed.

[3]Combined MOE = Oral NOAEL (25 mg/kg/day) / Daily Combined (Dermal + Inhalation) Dose.

[4] Mitigation Levels

Baseline: Long sleeve shirt, long pants, shoes/socks, no respirator

PPE - Baseline+Gloves/NR: Long sleeve shirt, long pants, shoes/socks, chemical resistant gloves, no respirator
PPE - Baseline+Gloves/80% R: Long sleeve shirt, long pants, shoes/socks, chemical resistant gloves, dust/mist respirator with a reduction factor of 80%

All occupational postapplication exposure scenarios had MOEs of concern (<100) at 0-day, except hand pinching woody ornamentals and bedding plants in greenhouses (Table 10). For all other scenarios, Restricted Entry Intervals (REIs) of 5-days to >20 days are required to achieve acceptable MOEs.

Table 10. Occupational Postapplication Exposure

Crops	Activities (Transfer Coefficient, cm^2/hr)	Maximum Application Rate (lb ai/acre)	MOE (Day 0)
Turf Maintenance (golf courses, recreational areas, sod farms, etc.)	Mowing, Seeding, Mechanical Weeding, Aerating, Fertilizing, Pruning (3400)	16	7.2
	Transplanting, Hand Weeding (6800)	16	3.6
Woody Ornamentals and Bedding Plants	Hand Pinching [greenhouse] (175)	3.9	140
	"Harvesting" [Reorganizing pots, loading plants onto trucks] (400)	3.9	63
Ferns	Harvesting (5100)	3.9	4.9

6. Occupational Incidents Reports

One occupational incident case was reported to the Poison Control Center in 1994 involving inhalation by a 23 year old adult male who reported a headache. Detailed descriptions of 17 cases involving chloroneb were submitted to the California Pesticide Illness Surveillance Program (1982-2002). In four of these cases, chloroneb was used alone or was judged to be responsible for the health effect. These four cases (1982-1988) involved: (1) a definitive case involving the eyes with no additional details reported; (2) a possible skin reaction in a worker planting cottonseed; (3) the development of nonspecific, systemic symptoms in a worker transporting cottonseed; and (4) acute bilateral conjunctivitis with possible chemical burn in a worker planting beans.

B. Environmental Risk Assessment

The Agency has conducted an environmental assessment for chloroneb for the purposes of making a reregistration decision. The Agency evaluated environmental fate and ecological studies submitted for chloroneb and determined that the data are adequate to support a reregistration decision. More in depth

details of the toxicity to aquatic and terrestrial organisms and fate and persistence studies used to develop the risk assessments and to support the guidelines are provided in the environmental risk assessment and in separate disciplinary chapters associated with this document. These documents are provided in the electronic docket. A summary of the environmental risk assessment findings and conclusions are provided in the following subsections below.

1. Environmental Fate and Transport Properties

The assessment of the fate and transport properties of chloroneb is based upon an incomplete data set. Therefore, there are uncertainties associated with the fate and transport behavior of chloroneb and its major degradates. Based on available data, chloroneb is expected to leach to ground water under sandy soils, as degradation would be expected to slow down when chloroneb leaches below the root zone. Chloroneb is mobile and is expected to be transported to surface water, through runoff.

2. Ecological Risk Assessment

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the quotient method. Risk quotients (RQs) are a screening level for potential risk and calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to levels of concern (LOCs). Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

3. Risks to Aquatic Animals

Acute risk to non-endangered freshwater fish and invertebrates is below the Agency's level of concern for chloroneb seed treatment uses and the uses on ornamentals. The golf course turf and ornamental turf uses are also below the acute level of concern, however, they exceed the restricted use and endangered species levels of concern for freshwater organisms. The risks to aquatic-phase amphibians are assessed using freshwater fish as a surrogate; the risk to amphibians are assumed to be the same as those to freshwater fish. No chronic aquatic toxicity data have been submitted for freshwater aquatic species. Therefore, the Agency cannot dismiss the possibility that there are chronic risks for freshwater fish, amphibians, and invertebrates for all registered uses of chloroneb. In addition, no acute or chronic toxicity data have been submitted to assess risk to estuarine and marine organisms to chloroneb. As a result, the screening level assessment cannot dismiss the possibility that there are acute and chronic risks to estuarine and marine species for all registered uses of chloroneb.

4. Risk to Terrestrial Animals

For avian species, although the acute and restricted use levels of concern exceed for some uses based on maximum application rates, the Agency considers it unlikely that non-endangered avian species are at risk from use of chloroneb. Because there is no acute toxicity endpoint established (the avian LD50 was >5000 ppm) and because of the conservative nature of the risk assessment process it was assumed that the exceedances do not represent 'actual' exceedances. Risks to endangered avian species, however, cannot be dismissed for any of the uses because there was some mortality noted in the bobwhite quail acute toxicity study at the lowest dose tested (156 ppm). There were no data to assess the potential chronic effects to avian species, therefore, the Agency cannot dismiss the possibility that there are chronic risks to birds. The risks to reptiles and terrestrial phase amphibians are assessed by using birds as a surrogate, so risks to these species are assumed to be the same as those to birds.

The acute oral LD50 in rats and acute dermal LD50 in rabbits were both >5000 ppm, therefore, chloroneb is considered practically non-toxic to mammals. However, other relevant acute and no chronic mammalian toxicity data were submitted on chloroneb. As a result, the risks to mammals could not be fully assessed. Therefore, the Agency cannot dismiss the possibility that there are acute and chronic risks to mammals for all registered uses of chloroneb. In addition, no data were submitted on the toxicity of chloroneb to bees. As a result, risks to terrestrial invertebrates from foliar uses of chloroneb (golf course turf, ornamental turf, and ornamental) cannot be precluded.

5. Risks to Plants

Plant toxicity data are required when there is some indication that there may be significant toxicity to plants. These indicators may be a herbicidal mode of action, or statements on the label indicating toxicity to plants. None of these indicators are present for chloroneb, and no plant toxicity data have been submitted by the registrant. Therefore, the risks to plants (terrestrial or semi-aquatic) were not assessed.

6. Endangered Species

The screening level risk assessment for endangered species indicates that chloroneb either exceeds the endangered species LOCs or that data are lacking to assess risks for endangered species, as follows:

- Avian, and thus, reptiles and terrestrial phase amphibians (based on RQ exceedance of the acute LOC, and absence of relevant chronic data)

  Cotton and sugar beets: seed treatment- RQ exceedance of the acute LOC
  Turf and ornamentals: foliar application- RQ exceedance of the acute LOC
  Remaining uses- absence of relevant chronic data

- Mammals (based on absence of relevant acute and chronic toxicity data)
  All uses- absence of relevant acute and chronic toxicity data

- Freshwater fish and invertebrates, and, thus, aquatic phase amphibians (based on RQ exceedance of the acute LOC, and absence of chronic data)
  Turf: foliar application- RQ exceedance of the acute LOC
  Remaining uses- absence of relevant chronic data

- Estuarine/marine fish and invertebrates (based on absence of relevant acute and chronic toxicity data)
  All uses- absence of relevant acute and chronic toxicity data

These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

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 reviewed all available scientific data for chloroneb and has determined that the data are sufficient to support reregistration of all products containing chloroneb.

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient chloroneb. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient, chloroneb, the Agency has sufficient information on the human health and ecological effects of chloroneb to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that chloroneb containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (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 chloroneb that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of chloroneb, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data or data that are needed to confirm the decisions presented here.

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

chloroneb. If all changes outlined in this document are incorporated into the product labels, then all current risks for chloroneb will be adequately mitigated for the purposes of this determination under FIFRA. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in section D.3 below.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for chloroneb. During the public comment period on the risk assessments, which closed on July 25, 2005, the Agency received comments from 11 commentors: 1) The technical registrant, Kincaid Inc., had comments related to the uses, use rates and number of applications for uses that they are supporting; 2) PBI/Gordon's Corporation, an end-use product formulator, included comments related to the use on golf courses and proposals for possible risk mitigation; 3) the National Cotton Council indicated that chloroneb is one of the important fungicides that can be used as a seed treatment for cotton planting seed; 4) the Golf Course Superintendents Association of America (GCSAA) indicated that they support the continued use of chloroneb on golf courses, and that chloroneb provides rapid control of Pythium. There were also comments from other concerned citizens that pertained to risk assessment methods and endpoints. These comments in their entirety are available in the public docket (OPP-2004-0346) at http://www.epa.gov/edockets. Detailed Responses to Comments are available in the public docket (OPP-2004-0369).

The RED and technical supporting documents for chloroneb are available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket identification (ID) number OPP-2004-0369. The public may access EPA Dockets at http://www.epa.gov/edockets. In addition, the chloroneb 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 this pesticide. EPA has determined that risk from dietary (food and water sources) exposure to chloroneb is within its own "risk cup." An aggregate assessment was conducted for exposures through food, drinking water, and residential uses. The Agency has determined that the human health risks from these combined exposures are within acceptable levels with the mitigation cited below. In other words, EPA has concluded that the tolerances for chloroneb meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and

children.

b. Determination of Safety to U.S. Population (Including Infants and Children)

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

No special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from chloroneb residues, the Agency considered the nature of the effects observed in available studies, and other information. Thus, the special FQPA safety factor has been removed (i.e., reduced to 1X) for chloroneb based on no residual uncertainties for prenatal toxicity. However, an FQPA Database uncertainty factor has been retained due to the lack of an acceptable reproductive toxicity study.

c. 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. For 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. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on chloroneb, there was no estrogen and/or androgen mediated toxicity; however, there was increased moderate-severe thyroid histopathology in both the rat and dog, which was characterized as "increased activity", without further characterization as to c-cell or follicular cell origin.

When additional appropriate screening and/or testing protocols being considered under the

Agency's EDSP have been developed, chloroneb may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of chloroneb. 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 chloroneb.

2. Tolerance Reassessment Summary

A tolerance summary is presented below in table 11. The tolerances listed in 40 CFR §180.257(a) are expressed in terms of chloroneb (1,4-dichloro-2,5-dimethoxybenzene) and its metabolite (DCMP) 2,5-dichloro-4-methoxyphenol (calculated as chloroneb). The tolerance expression should be amended to include residues of the conjugate of 2,5-dichloro-4-methoxypheno.

Table 11. Tolerance Reassessment Summary for Chloroneb.

Commodity	Current Tolerance (ppm) [1]	Tolerance Reassessment (ppm) [2]	Comment/*[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.257 (a):			
Bean	0.1(N)	0.2	[*Bean, succulent*] [*Bean, seed*] Given the validated limit of quantitation for residues of chloroneb and DCMP in/on plants the tolerance will be set at 0.2 ppm.
Bean, forage	2	2	[*Cowpea, forage*]
Beet, sugar, roots	0.1(N)	0.2	Given the validated limit of quantitation for residues of chloroneb and DCMP in/on plants the tolerance will be set at 0.2 ppm
Beet, sugar, tops	0.1(N)	0.2	Given the validated limit of quantitation for residues of chloroneb and DCMP in/on plants the tolerance will be set at 0.2 ppm
Cotton, forage	2	Revoke	EPA no longer requires tolerances for cotton forage.

Table 11. Tolerance Reassessment Summary for Chloroneb.			
Commodity	Current Tolerance (ppm) [1]	Tolerance Reassessment (ppm) [2]	Comment/*[Correct Commodity Definition]*
Cotton, undelinted seed	0.1(N)	0.2	Given the validated limit of quantitation for residues of chloroneb and DCMP in/on plants the tolerance will be set at 0.2 ppm
Soybean	0.1(N)	0.2	Given the validated limit of quantitation for residues of chloroneb and DCMP in/on plants the tolerance will be set at 0.2 ppm
Soybean, forage	2	2	
Cattle, fat	0.2	To Be Determined (TBD)[3]	Ruminant metabolism data are required to confirm the nature and amount of the residues in meat and milk.
Cattle, meat	0.2		
Cattle, meat byproducts	0.2		
Goat, fat	0.2		
Goat, meat	0.2		
Goat, meat byproducts	0.2		
Hog, fat	0.2		
Hog, meat	0.2		
Hog, meat byproducts	0.2		
Horse, fat	0.2		
Horse, meat	0.2		
Horse, meat byproducts	0.2		
Milk	0.05(N)		
Sheep, fat	0.2		
Sheep, meat	0.2		
Sheep, meat byproducts	0.2		
Tolerances to Be Proposed under 40 CFR 180.257(a):			
Cotton, gin byproducts	None established	1	
Cowpea, hay	None established	2	
Soybean, hay	None established	2	
Cottonseed, oil	None established	TBD	Cottonseed oil and soybean oil data are required; otherwise, tolerances should be set on cottonseed oil and soybean oil at 1 ppm and 2 ppm, respectively, based on maximum theoretical estimates..
Soybean, oil	None established		

[1] (N) = Negligible residues.

[2] Reassessed tolerances are based on the available plant metabolism and magnitude of the residue data taken as a whole. Residues of concern in/on bean, undelinted cottonseed, soybeans, sugarbeet roots and sugarbeet tops are not expected to exceed 0.1 ppm; however, reassessed tolerance levels for these commodities are set at

the validated LOQ of the enforcement method for residues of chloroneb and DCMP (free and conjugated), 0.2 ppm (total).

[3] The Agency has no dietary, drinking water, or residential risk concerns associated with these tolerances and consider them reassessed at the current tolerance level. The "TBD" designation is used, however, to convey that the Agency expects that the data required in the DCI that will be issued as a result of this RED will confirm that conclusion.

D. Regulatory Rationale

The Agency has determined that chloroneb is eligible for reregistration provided that: additional required data are submitted to confirm this decision; the risk mitigation measures outlined in this document are adopted; and, label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of chloroneb. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Aggregate Risk Mitigation

1) Short-/Intermediate Term Aggregate Risk Mitigation

Short term exposure to chloroneb may occur after application at homes (commercially treated home lawns); or after applications at golf courses, parks, schools, or other areas where chloroneb may be applied to turf.

To mitigate residential post-application risks to children and adults, the registrant has agreed to voluntarily cancel the use of chloroneb on residential lawns and turf, as well as on lawns and turf in parks and at schools. In addition, the registrant has agreed to amend labeling to remove all other turf uses pending receipt, review, and acceptance of a 21-day dermal toxicology study and reevaluation of risk. Risk will be re-evaluated using the following revised use patterns/restrictions, which have been agreed upon by the registrant.

- restriction of use on turf to golf course tees, greens, collars, aprons, and spot treatment of fairways, as well as professional athletic turf (football, baseball fields, etc.).

- limit the number of applications on golf courses to 6 per year; 4 applications at 7 lb ai/A and 2 applications at 16 lb ai/A.

- limit maximum use per year on golf courses to 60 lb ai/acre/year.

- require a minimum retreatment interval of 14 days for golf course tees, greens, and aprons, and professional athletic fields.

b. Occupational Risk Mitigation

1) Handler Exposure

Handlers may be exposed to chloroneb while mixing, loading or applying chloroneb pesticides. A number of occupational handler exposure scenarios, even after the inclusion of the highest possible PPE level (not including engineering controls), have MOEs of concern (<100). These scenarios include:

- all mixer/loader/application scenarios for turf/woody ornamentals/bedding plants/ferns

- mixing/loading wettable powder for groundboom application on turf

- all loader/applicator scenarios for the use of wettable powder (WP) formulations in commercial seed treatments

- loading/applying liquid and multiple activities for commercial soybean seed treatment

- all on-farm seed treatment scenarios except sugar beets.

To mitigate the occupational handler risks, as well as occupational and residential postapplication risks, the registrant has agreed to amend its label to remove turf, ornamentals, bedding plants and ferns, as well as on-farm seed treatment use sites pending the Agency receipt, review, and acceptance of a 21-day dermal toxicology study and reevaluation of risk.

To mitigate the occupational risk from loading for commercial seed treatment, the registrant has agreed to replace the wettable powder formulation with the use of a water soluble packaging, and a closed loading system when loading/applying liquid for commercial seed treatment. The MOE's using engineering controls for these occupational scenarios are shown in Table 12.

Table 12. Occupational Risk from Commercially Treated Seed

Exposure Scenario	Crop Target	Application Rate (lb ai/lb seed)	Combined MOE
Loader/Applicator			
Wettable Powder in Water Soluble Packages for Commercial Seed Treatment	cotton	0.004875	110

Table 12. Occupational Risk from Commercially Treated Seed			
Exposure Scenario	**Crop Target**	**Application Rate (lb ai/lb seed)**	**Combined MOE**
	soybeans	0.001875	130
	beans, other	0.001875	230
	sugar beets	0.002438	390
Loading/Applying Liquid in Closed Loading System for Commercial Seed Treatment	soybeans	0.001875	150
Multiple Activities			
Multiple Activities for Commercial Seed Treatment	soybeans	0.001875	>100

2) Post-application Risk Mitigation

Workers may be exposed to chloroneb upon entering areas which have been previously treated with chloroneb to perform specific work activities in these areas (e.g., mowing, seeding, harvesting).

To mitigate these handler and occupational and residential post-application risks, the registrant has agreed to amend its label to remove turf, ornamentals, bedding plants and ferns, as well as on-farm seed treatment from its label pending the Agency receipt, review, and acceptance of a 21-day dermal toxicology study and reevaluation of risks. Appropriate REIs will be determined considering the additional revised use patterns/restrictions below which have also been agreed upon by the registrant.

- restriction of use on turf to golf course tees, greens, collars, aprons, and spot treatment of fairways, as well as professional athletic turf (football, baseball fields, etc.)

- limit the number of applications on golf courses to 6 per year; 4 applications at 7 lb ai/A and 2 applications at 16 lb ai/A

- limit maximum use per year on golf courses to 60 lb ai/acre/year
- require a minimum retreatment interval of 14 days for golf course tees, greens, and aprons, and professional athletic fields.

2. Environmental Risk Mitigation

As described above, the registrant has agreed to voluntarily cancel the use of chloroneb on residential lawns and turf, as well as on lawns and turf at parks and schools. In addition, the registrant has agreed to:

- restrict remaining turf use to golf course tees, greens, collars, aprons, and spot treatment of fairways, as well as professional athletic turf (football, baseball fields, etc.)

- limit the number of applications on golf courses to 6 per year; 4 applications at 7 lb ai/A and 2 applications at 16 lb ai/A

- limit maximum use per year on golf courses to 60 lb ai/acre/year

- require a minimum retreatment interval of 14 days for golf course tees, greens, and aprons, and athletic professional fields.

No significant risks were identified to terrestrial or aquatic species. However, the data base is poor. Additional data will be required as a follow-up to ths RED. The use restrictions and cancellations described above are expected to significantly reduce exposure to wildlife. No additional mitigation is required at this time. However, these mitigation measures do not eliminate the acute risks to endangered freshwater animals or birds for turf uses.

3. Endangered Species Considerations

The preliminary ecological risk assessment indicates that chloroneb exceeds the endangered species LOCs for the turf uses for freshwater fish and invertebrates, as well for most uses for birds. Chronic risks to endangered freshwater organisms can not be dismissed due to a lack of data. In addition, due to a lack of relevant toxicity data for mammals and marine/estuarine organisms, the screening level assessment cannot dismiss the possibility that there are acute and chronic risks for these endangered species.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered species, and to implement mitigation measures that address these impacts. The Endangered Species Act 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 then considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, this species-specific analysis will also consider the risk mitigation measures that are being implemented as a result of this RED.

Following this future species-specific analysis, a determination that there is a likelihood of potential effects to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. If the Agency determines use of chloroneb "may effect" 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 chloroneb at levels of concern. EPA is not requiring specific chloroneb 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 Program.

4. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, the Agency will continue to work with all interested parties on this important issue.

From its assessment of chloroneb, as summarized in this document, the Agency concludes that no additional drift management measures are needed for chloroneb. In the future, chloroneb product labels may be revised to include additional or different drift label.

V. What Registrants Need to Do

The Agency has determined that chloroneb is eligible for reregistration provided that (i) additional data that the Agency intends to require to confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 14). The additional data requirement that the Agency intends to obtain will include, among other things, submission of the following:

For chloroneb technical grade active ingredient products, registrants need to submit the following items.

Within 90 days from receipt of the generic data call-in (DCI):

1. Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
2. Any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Wilhelmena Livingston at (703) 308-8025 with questions regarding generic reregistration:

By US mail:
Document Processing Desk (DCI/SRRD)
Wilhelmena Livingston
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk
Wilhelmena Livingston
US EPA (7508C)
1801 Bell Street
Arlington, Virginia 2202

For end-use products containing the active ingredient chloroneb, registrants need to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. Any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. Two copies of the confidential statement of formula (EPA Form 8570-4);

2. A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration;"

3. Five copies of the draft label incorporating all label amendments outlined in Table 14 of this document;

4. A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

5. If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. The product-specific data responding to the PDCI.

Please contact Bonnie Adler (703) 308-8523 with questions regarding product reregistration and/or the PDCI. Address all materials submitted in response to the PDCI to:

By US mail:
Document Processing Desk (PDCI/PRB)
Bonnie Adler
US EPA Office of Pesticide Programs
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

By express or courier service only:
Document Processing Desk (PDCI/PRB)
Bonnie Alder
US EPA Office of Pesticide Programs
1801 Bell Street
Arlington, Virginia 22202

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic database supporting the registration of chloroneb has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and included in the generic DCI for this RED (Table 13).

Table 13. Data Requirements for the Reregistration Eligibility Decision on Chloroneb

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
21-day dermal toxicity study in rats	870.3200	82-2
90-day inhalation study	870.3465	82-4
2-generation rat reproduction study	870.3800	83-4
18-month mouse carcinogenicity study	870.4200b	83-2b
2-year rat chronic toxicity/carcinogenicity study	870.4300	83-5
Mouse micronucleus assay	870.5395	84-2
General Metabolism - rat	870.7485	85-1
Processed Food/Feed Cottonseed oil and soybean oil processing data are required; otherwise, tolerances of 1 ppm and 2 ppm will be established for cottonseed oil and soybean oil, respectively, based on the maximum residue estimates in these processed commodities.	860.1520	171-4l
Nature of the Residue - Animals Ruminant metabolism data only.	860.1300	81-3
Multiresidue Methods Recovery data for the metabolite DCMP.	860.1360	171-4m
Submittal of Analytical Reference Standards Submission of a reasonable amount of the analytical reference standards for DCMP to the Pesticide Repository. Standards for chloroneb and metabolites must be replenished as requested by the Repository.	860.1650	171-13
Confined Accumulation in Rotational Crops Rotational crop data are required; otherwise, a 12-month plant back interval is required for all unregistered crops.	860.1850	165-1

Table 13. Data Requirements for the Reregistration Eligibility Decision on Chloroneb		
Guideline Study Name	**New OPPTS Guideline No.**	**Old Guideline No.**
Product Identity and Composition	830.1550	61-1
Certified Limits	830.1750	62-2
Stability to Metals	830.6313	63-13
Oxidation/Reduction	830.6314	63-14
Explodability	830.6316	63-16
Storage Stability	830.6317	63.17
Corrosion Characteristics	830.6320	63-20
UV/Visible Absorption	830.7050	none
Vapor Pressure	830.7950	63-9
Avian Reproduction-Bobwhite quail and Mallard Duck	850.2300	71-4
Freshwater Fish Acute LC_{50} Rainbow Trout and Bluegill Sunfish	850.1075	72-1
Estuarine/Marine Fish Acute LC_{50} (Sheepshead minnow)	850.1075	72-3a
Estuarine/Marine Acute Invertebrate LC_{50} (Mysid shrimp)	850.1035	72-3b
Estuarine/Marine Acute Invertebrate LC_{50} (Mollusk)	850.1025	72-3c
Daphnid chronic toxicity test	850.1300	72-4
Fish- early life stage toxicity test	850.1400	72-4
Mysid chronic toxicity test	850.1350	72-4
Terrestrial Field Dissipation	835.6100	164-1

2. Labeling for Technical and Manufacturing End-Use Products

To ensure compliance with FIFRA, technical and manufacturing use products (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The technical and MP labeling should bear the labeling contained in Table 14 Label Changes Summary Table.

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 pesticides after a determination of eligibility has been made. The registrant must review previous data submissions to ensure 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 Registrations Response form provided for each product.

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

2. Labeling Requirements for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 14.

a. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. Table 14 describes how language on the labels should be amended.

C. Existing Stocks

Existing stocks time frames will be established case by case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," Federal Register, Volume 56, No. 123, June 26, 1991.

Table 14: Summary of Labeling Changes for Chloroneb

Label requirements for the following uses may be revised from current labels based on the 21-day dermal toxicity study required by the Agency and included in the chloroneb data call-in: Turf, ornamentals, bedding plants, ferns, and on-farm seed treatment. Until the dermal toxicity study is received by the Agency and risks reevaluated and deemed acceptable, the registrant has agreed to remove these use sites from product labeling.

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products (MUPs)	"Only for formulation into a fungicide for the following use(s) [fill blank only with those uses that are being supported by MUP registrant]." For MUPs intended for seed treatment use: "For use in commercial seed treatment establishments." "Wettable powder end use product formulations must be packaged in water soluble packages."	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	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the 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."	Precautionary Statements

End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED for liquid formulations and wettable powder formulations packaged in water soluble packages intended for use in commercial seed treatment	"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 sleeved shirt, long pants - socks plus shoes, - chemical resistant gloves, except for persons participating in bagging and sewing, - and a chemical-resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate. See engineering controls for additional requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"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 Controls for liquid formulations used in commercial seed treatments	"Engineering Controls **"Mixers and loaders must use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people *AND* the system must be functioning properly and must be used and maintained in accordance with the manufacturer's written operating instructions. In addition, mixers and loaders must:** — wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders, — wear protective eyewear if the system operates under pressure, and — be provided, must have immediately available, and must use in an emergency, such as a broken package, spill, or equipment breakdown: – chemical-resistant footwear, and – a 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." * ***Instruction to Registrant***: Drop the "N" type prefilter from the respirator statement if the product contains, or is used with, oil."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Engineering Controls for wettable powder formulations packaged in water soluble packets used in commercial seed treatments	"Engineering Controls Water-soluble packets when used correctly qualify as a closed mixing/loading system. Mixers and loaders using water-soluble packets must: — wear the personal protective equipment specified in the PPE section of this labeling for mixers and loaders, and — be provided, have immediately available, and must use in an emergency, such as a broken package, spill, or equipment breakdown: – chemical-resistant footwear, and – a 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." * ***Instruction to Registrant***: Drop the "N" type prefilter from the respirator statement if the product contains, or is used with, oil."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE 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 for products used in seed treatments	"Environmental Hazards" "This product is toxic to aquatic organisms. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters."	Precautionary Statements under Environmental Hazards
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.

Application Restrictions for products used for seed treatments	**For seed treatments:** "Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag:" – "This bag contains seed treated with chloroneb. Persons opening this bag or loading/pouring the treated seed must wear long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves, and a NIOSH-approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC 21C, *or* any N*, R, P, or He filter." – "Treated Seed - Do Not Use for Food, Feed, or Oil Purposes." – "After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. Exception: Once seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no contact with the soil/media subsurface." * ***Instruction to Registrant***: Drop the "N" type prefilter from the respirator statement if the product contains, or is used with, oil.	Directions for Use under General Precautions and Restrictions and/or Application Instructions

VI. APPENDICES

Appendix A: CHLORONEB USE PATTERNS ELIGIBLE FOR REREGISTRATION

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
BEANS	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate food or feed. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction) Do not use in homes. Do not use treated seed for feed, food or oil purposes. This product is toxic to fish. Seed Treatment Application rates are not to exceed 7.8 oz AI/cwt seed of cotton or 3.0 oz AI/cwt on beans, soybeans or sugar beets.					
At planting Seed treatment Seed treater	0.1586 lb cwt	NS	NS	NS	NS	
Preplant Seed treatment Hopper box	0.1586 lb cwt	NS	NS	NS	12 h	
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
BEANS, DRIED-TYPE	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Seed Treatment Application rates are not to exceed 7.8 oz AI/cwt seed of cotton or 3.0 oz AI/cwt on beans, soybeans or sugar beets.					
At planting Seed treatment Drill box/Planter/seed box	0.1586 lb cwt	NS	NS	NS	12 h	
Preplant Seed treatment Hopper box	0.1586 lb cwt	NS	NS	NS	12 h	
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	
BEANS, SUCCULENT (LIMA)	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.					

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Seed Treatment Application rates are not to exceed 7.8 oz AI/cwt seed of cotton or 3.0 oz AI/cwt on beans, soybeans or sugar beets.					
At planting Seed treatment Drill box/Planter/seed box	0.1586 lb cwt	NS	NS	NS	12 h	
Preplant Seed treatment Hopper box	0.1586 lb cwt	NS	NS	NS	12 h	
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	
BEANS, SUCCULENT (SNAP)	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal.					

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Seed Treatment Application rates are not to exceed 7.8 oz AI/cwt seed of cotton or 3.0 oz AI/cwt on beans, soybeans or sugar beets.					
At planting Seed treatment Drill box/Planter/seed box	0.1586 lb cwt	NS	NS	NS	12 h	
Preplant Seed treatment Hopper box	0.1586 lb cwt	NS	NS	NS	12 h	
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	
COTTON (UNSPECIFIED)	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate food or feed. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)					

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not use in homes. Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. This product is highly toxic to birds, fish, and other wildlife. This product is toxic to fish. Seed Treatment Application rates are not to exceed 7.8 oz AI/cwt seed of cotton or 3.0 oz AI/cwt on beans, soybeans or sugar beets. Geographic disallowable: CA					
At planting Seed treatment Drill box/Hopper box/Planter/seed box/Seed treater	0.39875 lb cwt	NS	NS	NS	12 h	
Preplant Seed treatment/Slurry Hopper box	0.3852 lb cwt	NS	NS	NS	12 h	Geographic allowable: East of Rocky Mtns West of Rocky Mtns
Seed Seed treatment/Slurry Mist-type seed treater/Slurry-type seed treater	0.3852 lb cwt	NS	NS	NS	12 h	Geographic allowable: East of Rocky Mtns West of Rocky Mtns
When needed Seed treatment Hopper box/Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	Geographic allowable: TX
COWPEA/BLACKEYED PEA	45 day(s) pregrazing interval.					

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.					
Preplant Seed treatment Hopper box	0.1586 lb cwt	NS	NS	NS	12 h	
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	
COWPEAS	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not use treated seed for feed, food or oil purposes.					
At planting Seed treatment	0.1586 lb cwt	NS	NS	NS	12 h	

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Drill box/Planter/seed box						
LUPINE	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.					
At planting Seed treatment Drill box/Planter/seed box	0.1586 lb cwt	NS	NS	NS	12 h	
Preplant Seed treatment Hopper box	0.1586 lb cwt	NS	NS	NS	12 h	
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	
LUPINE, GRAIN	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash					

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	waters. Do not contaminate water, food, or feed by storage or disposal. Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.					
At planting Seed treatment Drill box/Planter/seed box	0.1586 lb cwt	NS	NS	NS	12 h	
Preplant Seed treatment Hopper box	0.1586 lb cwt	NS	NS	NS	12 h	
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	
SOYBEANS (UNSPECIFIED)	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.					

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Seed Treatment Application rates are not to exceed 7.8 oz AI/cwt seed of cotton or 3.0 oz AI/cwt on beans, soybeans or sugar beets.					
At planting Seed treatment Drill box/Planter/seed box	0.1586 lb cwt	NS	NS	NS	12 h	
Preplant Seed treatment Hopper box	0.1586 lb cwt	NS	NS	NS	12 h	
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	0.1586 lb cwt	NS	NS	NS	12 h	
SOYBEANS, EDIBLE	45 day(s) pregrazing interval. Do not use treated seed for feed, food or oil purposes. Seed Treatment Application rates are not to exceed 7.8 oz AI/cwt seed of cotton or 3.0 oz AI/cwt on beans, soybeans or sugar beets.					
Seed Seed treatment Slurry-type seed treater	0.1031 lb cwt	NS	NS	NS	NS	
SUGAR BEET	Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal.					

SITE NAME	LIMITATIONS					
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	R E I	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not use treated seed for feed, food or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Seed Treatment Application rates are not to exceed 7.8 oz AI/cwt seed of cotton or 3.0 oz AI/cwt on beans, soybeans or sugar beets.					
Preplant Seed treatment Hopper box	0.1767 lb cwt	NS	NS	NS	12 h	
GOLF COURSE TURF	Restrict use on turf to golf course tees, greens, collars, aprons, and spot treatment of fairways, as well as professional athletic turf (football, baseball fields, etc.). Limit the number of applications on golf courses to 6 per year; 4 applications at 7 lb ai/A and 2 applications at 16 lb ai/A. Limit maximum use per year on golf courses to 60 lb ai/acre/year. Require a minimum retreatment interval of 14 days for golf course tees, greens, and aprons, and professional athletic fields. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not graze or feed clippings from treated areas to livestock.					
Foliar Broadcast Spreader	.1861 lb 1K sq.ft	NS	60 lb ai/acre/yr	14	NS	

Seedling stage Broadcast Spreader	.1861 lb 1K sq. ft	NS	60 lb ai/acre/yr	14	NS	
ORNAMENTAL HERBACEOUS PLANTS	Do not graze treated areas or use clippings from treated areas for feed or forage. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.					
Foliar Chemigation/Spray Overhead sprinkler irrigation/Solid set irrigation/Sprayer	3.9 lb A	NS	NS NS	30	12 h	
When needed Soil drench treatment Drencher	.001162 lb pot	NS	NS NS	NS	12 h	
ORNAMENTAL NONFLOWERING PLANTS	Do not graze treated areas or use clippings from treated areas for feed or forage. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.					
Foliar Chemigation/Spray Overhead sprinkler irrigation/Solid set irrigation/Sprayer	3.9 lb A	NS	NS NS	30	12 h	
When needed Soil drench treatment Drencher	.001162 lb pot	NS	NS NS	NS	12 h	
ORNAMENTAL WOODY SHRUBS AND VINES	Do not graze treated areas or use clippings from treated areas for feed or forage. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.					

Foliar Chemigation/Spray Overhead sprinkler irrigation/Solid set irrigation/Sprayer	3.9 lb A	NS	NS NS	30	12 h	
When needed Soil drench treatment Drencher	.001162 lb pot	NS	NS NS	NS	12 h	

PRODUCT NUMBERS CONTAINED IN THIS TABLE

002217-00692, 009198-00182, 009198-00204, 073782-00003, 001381-00166, 001381-00183, 002935-00413, 002935-00414, 007501-00068, 051036-00258, 073782-00002, 073782-00004

HEADER ABBREVIATIONS

Site Name - The site name refers to the entity (crop, building, surface or article) where a pesticide is applied and/or which is being protected.
Limitations - Precautionary statements related to the use of the product(s).
Application Timing - The timing of pesticide application and is the primary application sort (not aggregated).
Application Type - The type of pesticide application (aggregated).
Application Equipment - The equipment used to apply pesticide (aggregated).
Max. Single Appl. Rate to a Single Site - Maximum Dose for a single application to a single site. System calculated.
Max Seasonal Rate - The maximum amount of pesticide that can be applied to a site in one growing season (/cc) and during the span of one year (/yr).
Max. # Apps/cc & yr - Maximum Number of Applications per crop cycle and per year.
M R I - Minimum Retreatment Interval (days) (at any rate). The minimum interval between pesticide application (days).
R E I - ReEntry Interval - The minimum amount of time that must elapse before workers can reenter a treated area.
PHI/PGI/PSI Use Limitations (May not apply to all Reg.#s) - Preharvest/Pregrazing/Preslaughter Interval use limitations pertinent to the application.
Current As Of: - The label data for the listed products in this report is current of this date.

ABBREVIATIONS

AN - As needed
NA - Not Applicable
NS - Not Specified (on label)
(L) - The dosage information provided is from the label in terms of product (e.g., ounces, gallons, or pounds of the product) because there was insufficient information (e.g., missing density, area, or active ingredient percentages) to provide converted dosage information. This report provides active ingredient percentage in the product for the reported chemical for all unconverted label dosage information if this information is available. This active ingredient percentage information is displayed next to the form code abbreviations (e.g., 80% WP).

APPLICATION RATE

cwt : Hundred Weight
nnE-xx : nn times (10 power -xx), for instance, "1.234E-04" is equivalent to ".0001234"

Appendix B.

TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #0007 (chloroneb) covered by this RED. It contains generic data requirements that apply to chloroneb in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

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

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

A. Terrestrial food
B. Terrestrial feed
C. Terrestrial non-food
D. Aquatic food
E. Aquatic non-food outdoor
F. Aquatic non-food industrial

G. Aquatic non-food residential
H. Greenhouse food
I. Greenhouse non-food
J. Forestry
K. Residential
L. Indoor food
M. Indoor non-food
N. Indoor medical
O. Indoor residential

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

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Chloroneb

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	A,B,C,K	**43146602, Data Gap**
830.1600	61-2a	Start. Mat. & Mfg. Process	A,B,C,K	**43146602**
830.1620	61-2b	Description of Production Process	A,B,C,K	**00098323, 43146602**
830.1670	61-2b	Discussion of Impurities	A,B,C,K	**43146602**
830.1700	62-1	Preliminary Analysis	A,B,C,K	**43352401**
830.1750	62-2	Certification of limits	A,B,C,K	**43352402, Data Gap**
830.1800	62-3	Analytical Method	A,B,C,K	**43146603**
830.6302	63-2	Color	A,B,C,K	**43553701**
830.6303	63-3	Physical State	A,B,C,K	**43553702**
830.6304	63-4	Odor	A,B,C,K	**43553703**
830.6313	63-13	Stability - temp and ions	A,B,C,K	**43301106, Data Gap**
830.6314	63-14	Oxidation and Reduction	A,B,C,K	**43553700, Data Gap**
830.6315	63-15	Flammability	A,B,C,K	**43553700**
830.6316	63-16	Explodability	A,B,C,K	**43553700, Data Gap**
830.6317	63.17	Storage stability	A,B,C,K	**Data Gap**
830.6319	63-19	Miscibility	A,B,C,K	**43553700**
830.6320	63-20	Corrosion Characteristics	A,B,C,K	**43553700, Data Gap**
830.7000	63-12	pH	A,B,C,K	**43553700**

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Chloroneb

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
830.7050	none	UV/Visible absorption	A,B,C,K	**Data Gap**
830.7100	63-18	Viscosity	A,B,C,K	**43553700**
830.7200	63-5	Melting point/melting range	A,B,C,K	**43553704**
830.7220	63-6	Boiling point/range	A,B,C,K	**43553700**
830.7300	63-7	Density	A,B,C,K	**43301102**
830.7370	63-10	Dissociation Constants in Water	A,B,C,K	**43301104**
830.7550	63-11	Partial Coefficient, shake flask method	A,B,C,K	**43301105**
830.7840 830.7860	63-8	Water Solubility	A,B,C,K	**43301103**
830.7950	63-9	Vapor Pressure	A,B,C,K	**0000144, 43553700, Data Gap**
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Toxicology	A,B,C,K	**00001425, 00077314**
850-2200	71-2	Avian Subacute Dietary	A,B,C,K	**00021873, 00021874**
850.1075	72-1	Fish Acute Toxicity	A,B,C,K	**43156801**
850.1400	72-4	Fish- Early Life Stage	A,B,C,K	**00021875, Data Gap**
850.2300	71-4	Avian reproduction test	A,B,C,K	**Data Gap**
850.1075	72-3a	Estuarine/Marine Fish Acute LC50 (sheepshead minnow)	A,B,C,K	**Data Gap**

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Chloroneb

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
850.1035	72-3b	Estuarine/Marine Fish Acute LC50 (mysid shrimp)	A,B,C,K	**Data Gap**
850.1025	72-3c	Estuarine/Marine Fish Acute LC50 (mollusk)		**Data Gap**
850.1300	72-4	Daphnid chronic toxicity test	A,B,C,K	**Data Gap**
850.1350	72-4	Mysid chronic toxicity test	A,B,C,K	**Data Gap**
OCCUPATIONAL/RESIDUE EXPOSURE				
875.2100 and 875.2200	132-1a and b	Dissipation of Dislodgeable Foliar and Soil Residues	A,B,C,K	**Data Gap**
875.2400	133-3	Dermal Passive Dosimetry Exposure	A,B,C,K	**Data Gap**
875.2500	133-4	Inhalation Passive Dosimetry Exposure	A,B,C,K	**Data Gap**
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	A,B,C,K	**00032544**
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A,B,C,K	**00093893**
870.1300	81-3	Acute Inhalation Toxicity-Rat	A,B,C,K	**00004982**
870.2400	81-4	Primary Eye Irritation-Rabbit	A,B,C,K	**00004983**
870.2500	81-5	Primary Skin Irritation	A,B,C,K	**00032544**
870.2600	81-6	Dermal Sensitization	A,B,C,K	**00063019**

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Chloroneb

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
870.3100	82-1a	90-Day Feeding - Rodent	A,B,C,K	**00001446**
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A,B,C,K	**Data Gap 0001445**
870.3465	?	90-day inhalation	A,B,C,K	**Data Gap**
870.4100	83-1a	Chronic Feeding Toxicity - Rodent	A,B,C,K	**Reserved**
870.4100b	83-1b	Chronic Feeding Toxicity - Dog	A,B,C,K	**00001421**
870.4200b	83-2a	Oncogenicity - mouse	A,B,C,K	**Data Gap**
870.3700a	83-3a	Developmental Toxicity (Teratogenicity) - rat	A,B,C,K	**00131472, 42482401**
870.3700b	83-3b	Developmental Toxicity (Teratogenicity) - rabbit	A,B,C,K	**40711302**
870.3800	83-4	2-Generation Reproduction - Rat	A,B,C,K	**00001423, 00131471, Data Gap**
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	A,B,C,K	**00001422, 00093887, Data Gap**
870.5265		Gene Mutation - Ames Assay	A,B,C,K	**00093888**
870.5395		Mutagenicity - Structural chrom. aberration	A,B,C,K	**Data Gap**
870.5375		Gene Mutation - Mouse Lymphoma Assay	A, B, C, K	**43301101**
870.5375		Chinese hamster ovary/forward gene mutation assay	A,B,C,K	**00093890**
870.5550		Unscheduled DNA synthesis	A,B,C,K	**00104246**
870.5900		in vitro Cytogenetic assay	A,B,C,K	**00093889**

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Chloroneb

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
870.7485		General metabolism- rat	A,B,C,K	**Data Gap**
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A,B,C,K	**GS-0007-6**
835.2240	161-2	Photodegradation - Water	A,B,C,K	**43593501**
835.4100	162-1	Aerobic Soil Metabolism	A,B,C,K	**43670901**
835.1240	163-1	Leaching/Adsorption/Desorption	A,B,C,K	**43146601**
835.1100	164-1	Terrestrial Field Dissipation	A,B,C,K	**Data Gap**
RESIDUE CHEMISTRY				
860.1200		Directions for Use		
860.1300	171-4a	Nature of Residue in Plants	A,B,C,K	**00001407, 00001430, 00002218, 05001134, 05001158, 05001172, 05001181, 05001297, 05001302, 05001304, 43512701, 44643301, 44916801, GS0007-013**
860.1300	171-4b	Nature of Residue in Livestock	A,B,C,K	**Data Gap**
860.1340	171-4c	Residue Analytical Method - plant	A,B,C,K	**00001429, 00001434**
860.1340	171-4d	Residue Analytical Method - livestock	A,B,C,K	**00001429, 00001431**
860.1360	171-4m	Multiple Residue Methods	A,B,C,K	**Data Gap**
860.1480	171-4j	Residues on Meat/Milk/Poultry/Egg	A,B,C,K	**00001424, 00001431, 00002214, 05001156, 05001159**
860.1500	171-4k	Cropfield Residue (beet, sugar)	A,B,C,K	**00001412**
860.1500	171-4k	Cropfield Residue (beet, sugar, tops)	A,B,C,K	**00001412**

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Chloroneb

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
860.1500	171-4k	Cropfield Residue (Bean)	A,B,C,K	**00001412**
860.1500	171-4k	Cropfield Residue (Soybean, seed & aspirated grain fractions)	A,B,C,K	**00001412**
860.1500	171-4k	Cropfield Residue (Bean, forage & hay)	A,B,C,K	**00001412**
860.1500	171-4k	Cropfield Residue (Soybean, forage & hay)	A,B,C,K	**00001412**
860.1500	171-K	Miscellaneous Commodities (Cotton, seed and gin byproducts)	A,B,C,K	**00001412, 00001434**
860.1520	171-4 L	Processed Food/Feed (Beet, sugar)	A,B,C,K	**00001412, 00131470**
860.1520	171-4 L	Processed Food/Feed (Cotton)	A,B,C,K	**44643301, Data Gap**
860.1520	171-4 L	Processed Food/Feed (Soybean)	A,B,C,K	**44643301, Data Gap**
860.1650	171-13	Submission of Analytical Reference Standards	A,B,C,K	**Data Gap**
860.1850	165-1	Confined Accumulation in Rotational Crops	A,B,C,K	**Data Gap**

Appendix C: Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained preliminary risk assessments and related documents as of January 26, 2004. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" documents and the revised risk assessments to the docket on July 2, 2004. Following a third 60-day comment period, EPA further revised the EFED risk assessment, and added formal "Response to Comments" documents.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

http://docket.epa.gov/edkpub/index.jsp

These documents include:

Phase 4: Risk Mitigation for Occupational Exposure to Chloroneb in Commercial Seed Treatment Scenarios. September 26, 2005.

Revised Occupational Postapplication Exposure Risk Assessment for Chloroneb. September 29, 2005.

Chloroneb: Characterization of Potential Carcinogenic Risk from Dietary Exposure. September 21, 2005.

Request for Additional Information and Suggestions for the Reregistration of Chloroneb Phase 3 Public Comment Period.

Readers's Guide to the Chloroneb E-Docket.

Overview of Chloroneb Risk Assessments. May 25, 2005

Chloroneb: HED Chapter of the Reregistration Eligibility Decision Document. December 30, 2004.

Chloroneb: Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document. January 6, 2004.

Chloroneb: 1st Report of the Hazard Identification Assessment Review Committee. December 18, 2003.

Chloroneb: Product Chemistry Considerations for Reregistration Eligibility Decision. December 21, 2004.

Chloroneb: Residue Chemistry Considerations for Reregistration Eligibility Decision. December 21, 2004.

Chloroneb: Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision. December 21, 2004.

Tier 1 Drinking Water Exposure Assessment for Chloroneb. November 15, 2004.

Ecological Risk Assessment for the Reregistration of Chloroneb. December 31, 2004.

Review of Chloroneb Incident Report. May 18, 2004.

Response to Registrant's Comments on the Phase 3 Period of the Chloroneb RED Ecological Chapter. August 15, 2005

Chloroneb: Health Effects Division (HED) Response to the Phase 3 Public Comments on the HED Chapter of the Chloroneb Reregistration Eligibility Decision Document (RED). August 18, 2005

Appendix D. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE REREGISTRATION DECISION (BIBLIOGRAPHY)

GUIDE TO APPENDIX D

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

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

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

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

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

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

MRID	CITATION
1407	Rhodes, R.C. (1968?) Chemical Identification of Metabolites of Chloroneb in Bean Plants. (Unpublished study received Jul 8, 1968 under 8F0657; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091146-B)
1408	Hock, W.K.; Sisler, H.D. (1968) Metabolic Detoxification of Chloro- neb (1,4-Dichloro-2,5-Dimethoxybenzene) by~Rhizoctonia~ ~?solani~?. (Unpublished paper presented at the 25th Annual Meeting of Potamac ?sic| Division, American Phytopathological Society; Mar 27, 1968; available from author, Univ. of Maryland, College Park, Md., received Jul 8, 1968 under 8F0657; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091146-C)
1409	Rhodes, R.C. (1968?) Determination of 2,5-Dichlorohydroquinone and 2,5-Dichloroquinone Residues in Cow Urine. Undated method. (Unpublished study received Jul 8, 1968 under 8F0657; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091146-E)
1410	E.I. du Pont de Nemours & Company, Incorporated (1968) Chromatograms--Sugar Beets. (Unpublished study received Jul 8, 1968 under 8F0657; CDL:091146-F)
1411	E.I. du Pont de Nemours & Company, Incorporated (1968) ?Residue Data: Chloroneb|. (Unpublished study received Jul 8, 1968 under 8F0657; CDL:091146-G)
1412	E.I. du Pont de Nemours & Company, Incorporated (1967) Results of Tests on the Amount of Residue in Crops Grown in ?Chloroneb| Treated Soil. (Unpublished study received Jul 8, 1968 under 8F0657; CDL:091146-I)
1413	E.I. du Pont de Nemours & Company, Incorporated (1967) ?Demosan Efficacy Studies|. (Unpublished study including letter dated Sep 15, 1965 from R.E. Worley to Robert Sutton, received Jul 8, 1968 under 8F0657; CDL:091146-J)
1414	Goode, M.J. (1965) Rhizoctonia root and stem rot of beans. Arkansas Farm Research ?(?/Sep-Oct):7. (Also~In~unpublished submission received Jul 8, 1968 under 8F0657; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091146-K)
1415	?E.I. du Pont de Nemours & Company, Incorporated?| (1965) Phytopath Tests–1965: Vol. 21--p. 57-60. (Unpublished study received Jul 8, 1968 under 8F0657; CDL:091146-L)
1416	Natti, J.J. (1965) Fungicide Treatments of Soil for Control of Bean Root Rots. (Unpublished study received Jul 8, 1968 under 8F0657; prepared by New York State Agricultural Station, Dept. of Plant Pathology, submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091146-M)
1417	E.I. du Pont de Nemours & Company, Incorporated (1966?) ?Demosan Efficacy Studies on Beans|. (Unpublished study received Jul 8, 1968 under 8F0657; CDL:091146-N)

1418 ?E.I. du Pont de Nemours & Company, Incorporated?| (1966) Phytopath Tests–1966: Vol. 22--p.56,59;57,58. (Unpublished study received Jul 8, 1968 under 8F0657; CDL:091146-O)

1419 E.I. du Pont de Nemours & Company, Incorporated (1966?) ?Demosan Efficacy Studies on Peas, Soybeans and Sugarbeets|. (Unpub- lished study received Jul 8, 1968 under 8F0657; CDL:091146-P)

1420 Fielding, M.J.; Rhodes, R.C. (1967) Studies with C^14I Labeled Chloroneb Fungicide in Plants. (Unpublished paper presented at Beltwide Cotton Production--Mechanization Conference; Jan 9-13, 1967; Dallas, Tex.; received Jul 8, 1968 under 8F0657; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091146-Q)

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Appendix E. GENERIC DATA CALL-IN

Note that a complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

Appendix F. PRODUCT SPECIFIC DATA CALL-IN

Note that a complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

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

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

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

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

participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.
Twelve products were found which contain Chloroneb as the active ingredient. These products have been placed two batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

No Batch: Each product in this Batch should generate their own data.

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
	73782-2	65.0
	73782-3	65.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	1381-166	Chloroneb: 30.0 Metalaxyl: 3.5
	51036-258	Chloroneb: 30.0 Metalaxyl: 3.5

No Batch	EPA Reg. No.	Percent Active Ingredient
	1381-183	Chloroneb: 30.00 Mefenoxam: 2.01
	2217-692	65.00
	2935-413	Chloroneb: 23.50 TCMTB: 9.00
	2935-414	30.00
	9198-182	6.25
	9198-204	Chloroneb: 3.26 Thiophanate-methyl: 1.63

	73782-1	88.00
	73782-4	30.00

Appendix H. List of Registrants Sent this Data Call-In Notice

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@epamail.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 (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in 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 the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide 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' Web Site

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. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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 Web site.

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 Web site: ace.orst.edu/info/nptn.

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:

Date of receipt
EPA identifying number
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 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 and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.