United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-04-012
September 2005

Reregistration Eligibility Decision for Mancozeb

Reregistration Eligibility Decision

for

Mancozeb

List B
Case No. 0643

Approved By:

/S/

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September 20, 2005
Date

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Glossary of Terms and Abbreviations

ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EC	Engineering Control
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
G	Granular Formulation
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
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
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
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
SLN	Special Local Need (Registrations Under Section 24c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UF_{db}	Database Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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EXECUTIVE SUMMARY

EPA has completed its review of public comments on the revised mancozeb risk assessments and is issuing its risk management decision for mancozeb. There are currently 43 tolerances being reassessed for mancozeb. The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and additional information received. After considering the risks identified in the revised risk assessment, comments, and mitigation suggestions from interested parties, EPA developed its risk management decision for uses of mancozeb that pose risks of concern. As a result, the Agency has determined that mancozeb-containing products are eligible for reregistration provided that data needs are addressed, risk mitigation measures are adopted, and labels are amended accordingly. The decision is discussed fully in this document.

Mancozeb was first registered in the United States in 1948 as a broad spectrum fungicide. Mancozeb is used in agriculture, professional turf management, and horticulture. Mancozeb was previously registered for use on athletic fields and pachysandra, for pineapple propagation use, for foliar use on cotton, and for use on residential lawns, but these uses have since been voluntarily cancelled. Use on sod farms and golf courses, and well as use in home gardens may result in non-occupational (residential or recreational) exposures. Approximately 5.6 million pounds of mancozeb are used annually. The largest markets for mancozeb in terms of total pounds of active ingredient (lbs ai) are apples and potatoes. In terms of percent crop treated, the crops that are treated most frequently with mancozeb are potatoes (with 54 to 65% crop treated) and onions (with 50 to 65% crop treated). Mancozeb is also used extensively on apples, grapes, pears, tomatoes, and watermelons.

Mancozeb is a member of the ethylene bisdithiocarbamate (EBDC) group of fungicides, which includes the related active ingredients maneb and metiram. This document summarizes risk estimates for both mancozeb and its metabolite and environmental degradate ethylene thiourea (ETU). Mancozeb and two other EBDC fungicides, maneb and metiram, are all metabolized to ETU in the body and all degrade to ETU in the environment. Therefore, EPA has considered the aggregate or combined risks from food, water and non-occupational exposure resulting from mancozeb alone, ETU resulting from mancozeb use, and ETU from all sources (i.e., the other EBDC fungicides). The aggregate risk from ETU from all sources must be considered to reassess the tolerances for metiram, maneb and mancozeb.

Overall Risk Summary

Mancozeb dietary risks from food and drinking water sources are low and not of concern. Mancozeb risks as a result of residential or recreational exposures are of concern for toddlers, and athletes. Risks to toddlers are being mitigated with a pre-harvest interval requirement, and the registrants have requested that the athletic field use be cancelled. There are some risk concerns for some occupational handlers, which will be mitigated with additional personal protective equipment (PPE). In addition, some application restrictions are necessary to maintain a 24 hour restricted entry interval (REI). For ecological risks, mancozeb poses some acute and

chronic risks to birds and mammals, and which will be reduced with various mitigation measures, including cancelling the pachysandra use, increasing the turf application interval, providing targeted turf application rates by grass variety, and reducing the application rate in papayas. .

Dietary Risk

Acute, chronic, and cancer dietary (food only) risks from mancozeb, mancozeb-derived ETU, and ETU from all sources are below the Agency's level of concern. The drinking water exposure assessment for mancozeb addresses concentrations of ETU only, since mancozeb is not expected to remain in drinking water long enough to reach a location that would supply water for human consumption, whether from surface or groundwater sources. Estimated concentrations of ETU, for both surface and ground water sources of drinking water, are low and not of concern.

Residential Risk

Current uses of mancozeb that may result in exposure to mancozeb and ETU residues include use in home gardens, use on golf courses and athletic fields, and use on sod farms (the potential exposure to mancozeb is from residues remaining on transplanted turf). Risks to residential handlers and golfers are below the Agency's level of concern. Cancer risks to athletes on treated fields are of concern; however, registrants have requested that this use be cancelled. EPA's original phase 3 risk assessment indicated risks of concern for toddlers exposed to transplanted sod treated with mancozeb. Recognizing that potential risk, the maneb and mancozeb registrants voluntarily agreed to extend the time between treatment and harvesting of sod from one to three days. This 3 day prohibition on harvesting, combined with the logistics of transplanting turf and installation restrictions, effectively reduced the potential contribution from this use pattern to a level not of concern to the Agency.

Aggregate Risk/ETU

Aggregate risk refers to the combined risk from food, drinking water, and residential exposures. In addition, aggregate risk can result from one-time (acute), short-term and/or chronic (non-cancer and cancer) exposures, and considers exposures from mancozeb-derived ETU and ETU from all sources, depending upon the scenario assessed. Acute, short-term, and chronic (non-cancer) aggregate risks are low and not of concern. Aggregate cancer risk estimates are within a negligible risk range, and therefore no mitigation measures are needed.

Occupational Risk

Workers can be exposed to mancozeb and mancozeb-derived ETU through mixing, loading, and/or applying (handlers) the pesticide or re-entering treated sites. There are some risks of concern to handlers, in particular to workers mixing and loading for application to high rate crops (e.g., turf, pachysandra) and/or for high acreage application methods (i.e., aerial and chemigation applications), and to workers applying to high acreage crops. To mitigate these risk

concerns, additional personal protective equipment (PPE) are required on the product labels (e.g., PF5 respirator).

At the current restricted entry interval (REI) of 24 hours and use patterns on current labels, predicted cancer risks resulting from estimated ETU exposures exceed 10^{-6} for post-application high-end exposure scenarios for several use sites. However, none of these estimated exposures resulted in predicted cancer risks above the range of 10^{-5}. Long REIs are impractical for mancozeb because it is a fungicide that must be applied repeatedly for efficacy. In addition, cultural practices for many crops require reentry within a day of mancozeb application. Therefore, the Agency believes it its appropriate to maintain the existing 24 hour REI for most crops.

Ecological Risk

For terrestrial species, short-term or acute mancozeb risks are low to mammals, birds, and nontarget insects. However, the screening-level ecological risk assessment for terrestrial species indicates that some risk quotients exceed the chronic levels of concern (LOCs), especially from mancozeb applications to turf, papayas and ornamentals. Risk quotients for aquatic species (freshwater fish, freshwater invertebrates, and non-vascular plants) slightly exceed the screening level of concern. Currently, there is no data on estuarine/marine species to assess aquatic chronic risk. The Agency intends to require additional data as part of this RED to address these data gaps. To be more protective of species that may be exposed to mancozeb, the technical registrant has agreed to additional label changes to reduce potential risk, including canceling the pachysandra use, increasing the turf application interval and providing targeted application rates by grass variety, and reducing the application rate in papayas.

Endangered Species

Available screening-level information for mancozeb indicate a potential concern for chronic effects on listed species of birds and mammals, acute and chronic effects on listed species of freshwater fish and freshwater invertebrates, and acute effects on listed species of estuarine/marine fish should exposure actually occur. Although the RQs for estuarine/marine invertebrates and nonvascular aquatic plants exceed the Agency's level of concern, there are no federally listed species in these taxa. EPA does not currently have enough data to quantify risks for mancozeb at the screening level and therefore cannot preclude potential direct effects to the following taxonomic groups: aquatic and terrestrial plants and estuarine/marine organisms (chronic effects).

These findings are based solely on EPA's screening-level assessment and do not constitute "may effect" findings under the Endangered Species Act for any listed species. If the Agency determines that the use of mancozeb "may affect" listed species or their designated critical habitat, EPA will employ provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is complete, the risk mitigation measures being implemented

through this RED will reduce the likelihood that endangered and threatened species may be exposed to mancozeb at levels of concern.

Regulatory Decision

The Agency has determined that most uses of the active ingredient mancozeb are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted, and labels amendments are made to reflect these measures. The following uses of mancozeb are not eligible for reregistration and are being voluntarily canceled by registrants and deleted from all mancozeb labels: foliar use on cotton, use on pineapple seed pieces (for propagation), use on residential lawns/turf, use on athletic fields/turf, and use on pachysandra.

Mitigation Summary

The following mitigation measures must be implemented for mancozeb to be eligible for reregistration:

1) Use Restrictions

Turf

All Formulations

- Establish a 3 day preharvest interval (PHI) on turf grown on sod farms
- For sod, restrict the amount that can be used to a maximum of 4 applications per year and reduce the maximum rate from 19 lbs ai/A to 17.4 lbs ai/A (69.6 lbs ai/A/season)
- Extend application interval from 7 to 10 days to 10 to 14 days

Wettable Powder (WP) Formulation

- Delete sod farm use from WP labels
- Use engineering controls (water soluble packs) for WP used on turf (golf courses & industrial parks)

Liquid Formulations

- Prohibit the application of liquids aerially to golf courses or sod farms, and prohibit the application of liquids in chemigation systems to golf courses

Papaya

- Reduce application rate from 4 to 2 lb ai/A

Cut Flowers/Greenhouse Grown Ornamentals

- Limit number of applications to 20 per year

Sweet Corn

- Prohibit homeowner use (remove from homeowner label)

Human Flaggers

- Prohibit human flaggers or require mechanical flaggers with aerial application

2) Personal Protective Equipment

WP Formulation, All Crops Except Turf

- Require single layer PPE, with PF 5 respirator and gloves (except pilots, groundboom applicators, and airblast applicators)
- Require single layer PPE for pilots, groundboom applicators, and airblast applicators

WP Formulation, Turf

- Delete sod farm use from WP labels
- Require use of engineering controls (water soluble packs) for WP used on turf (golf courses & industrial parks)

WP Formulation, Seed Treatment

- Require single layer PPE, with PF 5 respirator and gloves (all handlers except sewers and baggers)
- Require single layer PPE for sewers and baggers
- Require application as a liquid slurry or mist

DF (All Crops) and Liquid Formulations (All Crops Except Turf)

- Require single layer PPE with gloves for all handlers except aerial, airblast, & groundboom applicators
- Require single layer, no gloves, for aerial, airblast, & groundboom applicators (to avoid contaminating cab)

Liquid Formulations (Turf)

- Require single layer PPE with gloves and a PF 5 respirator for handlers mixing and loading to support chemigation application to sod
- Prohibit the application of liquids aerially to golf courses or sod farms, and prohibit the application of liquids in chemigation systems to golf courses

Seed Treatment, Liquids

- Require single layer PPE, with gloves (all handlers except sewers and baggers)
- Require single layer PPE for sewers and baggers

Potato Seed-Piece Treatment, Dust Formulation

- Require engineering controls, i.e., dust collection equipment, for commercial loaders and applicators
- Require single layer PPE with gloves and a PF5 respirator for all on-farm handlers

3) Use Cancellations and/or Deletions (ineligible for reregistration)

- foliar use on cotton
- pineapple propagation use
- residential lawn use
- pachysandra
- athletic fields

Next Steps

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

I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA 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 3, 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. Mancozeb belongs to a group of pesticides called dithiocarbamates, which also includes the ethylenebis dithiocarbamate (EBDC) fungicides maneb and metiram. For the purposes of this reregistration eligibility decision (RED), EPA has concluded that mancozeb does not share a common mechanism of toxicity with other substances. The Agency reached this conclusion after a thorough internal review and external peer review of the data on a potential common mechanism of toxicity. For more information, please see the December 19, 2001 memorandum, *"The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity,"* which is available on the internet at http://www.epa.gov/oppsrrd1/cumulative/dithiocarb.pdf. However, the EDBCs share a common metabolite and degradate, ethylene thiourea (ETU), which is considered in this RED.

This document presents EPA's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the RED for mancozeb. 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. Section VI contains the Appendices, which list related information, supporting documents, and studies evaluated for the reregistration decision. The preliminary and revised risk assessments for mancozeb are available in the Office of Pesticide Programs (OPP) Public Docket, under docket numbers OPP-2004-0078 and OPP-2005-0176, respectively, on the Agency's web page, http://www.epa.gov/edockets.

II. Chemical Overview

A. Regulatory History

Mancozeb was first registered in the United States in 1948 for use on food and ornamental crops to prevent crop damage in the field and to protect harvested crops from deterioration in storage or transport. Mancozeb is one of several ethylenebis-dithiocarbamate pesticides known as EDBCs; this group of fungicides also includes maneb and metiram. The EDBCs and their common metabolite ethylene thiourea (ETU) have been the subject of two Special Reviews based on concerns about potential carcinogenic, developmental, and other chronic health risks.

In 1977, the Agency initiated a Special Review of pesticide product containing mancozeb and the other EBDCs. This Special Review concluded in 1982 with a *Final Determination (PD 4)* requiring risk reduction measures to prevent unreasonable adverse effects pending development and submission of additional data needed for improved risk assessment. These data included a market basket survey of residues of the EBDCs and their metabolite, ETU, in foods and additional toxicological data for ETU.

EPA issued the registration standard for mancozeb, *"Guidance for the Reregistration of Pesticide Products Containing Mancozeb as the Active Ingredient,"* in April 1987. The Agency also issued a Generic Data Call In (DCI) requiring data needed to complete the reregistration of mancozeb in April 1987. EPA completed an update to the registration standard for product and residue chemistry data requirements in August 1992. Additional DCIs for mancozeb were issued in March and October 1995 to require data to evaluate exposure to pesticide handlers and re-entry workers.

Another Special Review on mancozeb and the other EBDCs began in 1987. This review identified the EDBC metabolite ETU as a developmental toxicant and a probable human carcinogen. A *Notice of Preliminary Determination (PD 2/3)* was published in the *Federal Register* on December 20, 1989 (54 FR 52158). With the publication of a *Notice of Intent to Cancel and Conclusion of Special Review (PD 4)* in the *Federal Register* on March 2, 1992 (57 FR 7484), the Agency canceled all mancozeb and other EBDC products registered on the

following food/feed crops: apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips. The Agency concluded that the dietary risks of EBDCs exceeded the benefits for the canceled food/feed uses. EPA also established requirements for personal protective equipment for workers applying EDBC products.

The 1992 PD 4 specified that only the following mancozeb food uses would be eligible for continued registration, provided that specific label revisions were made and supporting residue data were submitted: apples, asparagus, bananas, barley, corn (field, pop, and sweet), cotton, crabapples, cranberries, cucumbers, fennel, grapes, melons (cantaloupe, casaba, Crenshaw, honeydew, and watermelon), oats, onions (dry bulb only), papaya, peanuts, pineapples, potatoes, quince, rye, sugar beets, squash (summer only), tomatoes, and wheat. In addition, the special review set the pre-harvest interval (PHI) for use on potatoes at 14 days for most states. The only exceptions to the 14 day PHI were Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Pennsylvania, Vermont, and Wisconsin, where EPA determined that disease pressures caused by late blight justified a three day PHI.

In 1993, the Agency began receiving requests from grower groups and a formal petition from the mancozeb registrants to amend the 1992 cancellation order to reinstate mancozeb registrations on carrots and celery, and to allow for a three day preharvest interval (PHI) in all states due to an alleged increase in the occurrence of late blight nationwide. The Agency has not determined whether the petition warrants a hearing under 40 CFR § 164 nor has it determined whether it will grant the attendant registration amendment requests. Although EPA has not reached any conclusions on the merits of the petition or the amendment requests, this RED considers the potential additional risks resulting from the reinstatement of the use on celery and carrots and from reducing the PHI for potatoes to three days nationally. This consideration is for informational purposes only and cannot be interpreted as an indication of the Agency's position on the petition or amendment requests.

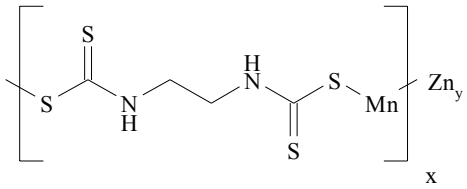
EPA has also received petitions for proposed new uses of mancozeb on ginseng, mandarin oranges (import tolerances), walnuts, and tropical fruits. These new uses are included in the risk assessment supporting this RED. However, because this RED evaluates only existing uses of mancozeb and reassesses only the currently established tolerances, the Agency will make determinations on the addition of new uses and the re-instatement of previously canceled uses in future decisions separate from the RED.

The Mancozeb Task Force was formed in 1994 to represent the interests of the Mancozeb registrants, who were then two companies: Rhom and Haas and E.I. DuPont De Nemours. Today, the Task Force represents the current mancozeb registrants, Dow AgroSciences, Griffin (now a DuPont subsidiary), and Cerexagri.

B. Chemical Identification

1. Mancozeb

Mancozeb [zinc manganese ethylenebis dithiocarbamate] is a fungicide registered for use on a variety of agricultural crops, ornamentals, and turf.



Common Name: Mancozeb

Trade Name: Dithane 45®, Manzate 200®, Penncozeb®, Fore

Chemical Name: Zinc Manganese ethylenebis dithiocarbamate

Chemical Family: Dithiocarbamate

Case Number: 0643

CAVES Registry Number: 8018-01-7

OPP Chemical Code: 014504

Molecular weight: $(265.3)_x + (65.4)_y$

Empirical Formula: $(C_4H_6MnN_2S_4)_x\ (Zn)_y$

Basic Manufacturers: Dow AgroSciences, Griffin LLC, and Cerexagri

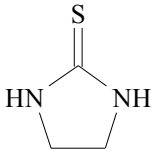
Mancozeb is a yellowish powder which decomposes at 150ºC, and has a density of 0.4 g/ml, actinal/water partition coefficient (P_{ow}) of 1.8, and negligible vapor pressure at 20ºC. Mancozeb is practically insoluble in water (13.6 g./ml), and most organic solvents. Mancozeb decomposes in acid and alkaline conditions, with heat, and upon exposure to moisture and air.

2. Ethylenethiourea (ETU)

Ethylenethiourea (ETU) is a metabolite, environmental degradate, and cooking byproduct of mancozeb and the other EBDC fungicides, maneb and metiram. Chemical information is

provided for ETU because many of the risk concerns for mancozeb and the other EBDCs are driven by risk from ETU.

Chemical Structure:



Chemical Name: Ethylene thiourea

CAVES Registry Number: 96-45-7

OPP Chemical Code: 600016

Molecular Weight: 102.2

Empirical Formula: $C_3H_6N_2S$

ETU is a crystalline solid with a white to pale green color, and a faint amine odor. It has a melting point of 203-204°C. ETU has an actinal/water partition coefficient of 0.22. ETU is considered soluble in water, with a water solubility of 20,000 PPE at 30°C, but it is also slightly soluble in methanol, ethanol, ethylene glycol, pyridine, acetic acid and naphtha. When ETU is heated to decomposition, nitrogen and sulfur oxides are emitted.

C. Use Profile

Mancozeb [zinc manganese ethylenebis dithiocarbamate] is a fungicide used in agriculture, professional turf management, and horticulture. Agricultural uses include pome fruit crops (e.g., apples, pears), fruits and vegetables (e.g., cucumbers, onions, tomatoes, and grapes), some high acre row crops (e.g., corn and potatoes), seed-piece treatment (e.g., potatoes), and seed treatment (e.g., rice, wheat, and cotton). Horticultural uses include ornamental plants in nurseries and greenhouses, sod farms, residential lawns and golf courses. A detailed table of mancozeb uses eligible for reregistration is contained in Appendix A.

Proposed new uses for mancozeb on ginseng, mandarins (import), walnuts, and tropical fruits were included in the risk assessments as well. In addition, the registrants have submitted a petition to reinstate celery and carrot uses in certain states and to decrease the potato pre-harvest interval under Subpart D of the Federal Insecticide, Fungicide, and Rodenticide Act. Although EPA has not reached any conclusions at this time on either the proposed new uses or the merits of the FIFRA Subpart D petition, these uses have been considered in this RED for informational purposes only. The Agency will issue decisions on these actions separately.

Type of Pesticide: Fungicide

Target Organism(s): Various fungal diseases, including anthracnose, blights, downy mildew, leaf spots, rusts, scabs, seed piece decay in potatoes, and smuts on seed.

Mode of Action: Contact fungicide (non systemic), disrupts cell metabolism at several sites in the target disease organism.

Use Sites: Mancozeb is registered for use on a variety of agricultural crops, fruit trees, ornamentals, and turf.

> **Food uses:** Apples, asparagus, cabbage, cantaloupe, cotton, cranberries, cucumber, eggplant, garlic, grapes, onions, peanuts, pears, pecans, potatoes, pumpkin, squash, sugar beets, sweet, corn, tobacco, tomatoes, watermelons, and wheat.
>
> **Non-Food & Residential Uses:** Turf and ornamentals, including use on nursery stock (e.g., nonbearing citrus) and in floriculture. Although registrants have requested deletion of use on residential lawns and turf, sod farm use remains. Registrants have requested deletion of use on pachysandra.
>
> **Public Health Uses:** None

Use Classification: General Use

Formulation Types: Wettable powders, dry flowables, flowables, and dusts.

Application Methods: Mancozeb can be applied with aerial or ground equipment, such as groundboom and airblast sprayers.

Application Rates: Mancozeb application rates vary by crop. There are approximately 110 active mancozeb labels. Of these, 63 are Special Local Need (FIFRA Section 24c) state-specific registrations. The label application rates in agriculture range from 1.2 lb active ingredient per acre (ai/A) for corn to 4.8 lb ai/A for pome fruits. The allowable number of applications per season ranges from 3 for cranberries to 15 for sweet corn and the application intervals range from 4 to 14 days. Some of the uses, such as grapes, have separate rates for eastern and western regions of the U.S. The application rates in horticulture range from 1.2 lb ai/A for most ornamentals (except pachysandra which has a rate of 14 lb ai/acre) to 19 lb ai/A for turf. Horticulture and turf applications are allowed as often as twice weekly with no annual limit.

Application Timing: Preplant; Pretransplant; At planting; Postemergence; Postplant; Posttransplant; Dormant; Delayed dormant; Delayed dormant through bloom; Delayed dormant through foliar; Before bud break; Bud break to fruit set; Prebloom; Bloom; Bloom through foliar;

Petal fall; Early jointing; Tillering; Early spring; Spring; Early summer; Late summer; Early fall; Winter; When needed.

Other Limitations: As a result of the Special Review, the Agency set usage limitations on the EBDC fungicides (mancozeb, maneb, and metiram) to establish consistency between the EBDC registrations and Market Basket Survey Data. The total poundage of all the EBDCs used on each crop must not exceed the maximum seasonal application rate for any one of these fungicides. The maximum season rate for all of EBDCs used is the same for most of the crops regardless of which EBDC is used, with the exception of cucurbits (cucumbers, melons, and summer and winter squash), for which the maximum rate per season depends upon which EBDC is used. The current maximum seasonal application rates for the EBDCs, by crop, are summarized in Table 1 below.

Table 1. Maximum EBDC Application Rates

Crop Group	Crop(s)	EBDC Used MZ = Mancozeb MN = Maneb MT = Metiram	Maximum Total Rate for all EBDC Fungicides (lb ai/acre)	
			Per Application	Per Season
Field Crops	Barley, Oats, Rye, Triticale, Wheat	MZ	1.6	4.8
Field Crops	Beans, Dry	MN	1.6	9.6
Field Crops	Corn: hybrid seedcorn	MZ, MN	1.2	12
Field Crops	Corn: field	MZ	1.2	12
Field Crops	Cotton	MZ	1.6	6.4
Field Crops	Peanuts	MZ	1.6	12.8
Field Crops	Sugar Beets	MZ, MN	1.6	11.2
Fruits	Bananas	MZ, MN	2.4	24
Fruits	Cranberries	MZ, MN	4.8	14.4
Fruits	Figs, Kodota	MN	2.4	2.4
Fruits	Grapes - West	MZ, MN	2	6
Fruits	Grapes- East	MZ, MN	3.2	19.2
Fruits	Papayas	MZ, MN	2	28
Fruits	Plantains	MZ	2.4	24
Miscellaneous	Christmas Trees, Douglas Fir	MZ	3.2	NA
Non-Food	tobacco fields	MZ	1.5	6
Non-Food	tobacco seedlings	MZ	2	None
Nut Crops	Almonds	MN	6.4	25.6
Ornamentals	Ornamentals, Pachysandra	MZ	13 -14	NA
Ornamentals	Ornamentals, Variety	MZ, MN	1.2 - 1.6	NA
Pome Fruits	Apples	MZ, MN, MT	2.4 or 4.8	16.8 or 19.2

Crop Group	Crop(s)	EBDC Used MZ = Mancozeb MN = Maneb MT = Metiram	Maximum Total Rate for all EBDC Fungicides (lb ai/acre)	
			Per Application	Per Season
Pome Fruits	Pears, Crabapples, Quince	MZ	2.4 or 4.8	16.8 or 19.2
Turf	Sod Farm	MZ, MN	16.3 - 19	NA
Turf	Golf Course, Athletic Fields	MZ	16.3 - 19	NA
Vegetables	Asparagus	MZ	1.6	6.4
Vegetables	Brassica	MN	1.6	9.6
Vegetables	Corn: sweet/pop/seed: East of Miss.	MZ, MN	1.2	18
Vegetables	Corn: sweet/ pop/seed: West of Miss.	MZ, MN	1.2	6
Vegetables	**Cucumbers**	**MZ, MN**	**MZ = 2.4** **MN = 1.6**	**MZ = 19.2** **MN = 12.8**
Vegetables	Fennel	MZ	1.6	12.8
Vegetables	Gourds: Edible	MZ	2.4	19.2
Vegetables	Lettuce	MN	1.6	6.4 (CA), 9.6 (US)
Vegetables	**Melons**	**MZ, MN**	**MZ = 2.4** **MN = 1.6**	**MZ = 19.2** **MN = 12.8**
Vegetables	Onions: Dry Bulb, Garlic	MZ, MN	2.4	24
Vegetables	Onions: Green	MN	2.4	11.2
Vegetables	Peppers	MN	1.6 (w), 2.4 (e)	9.6 (w), 14.4 (e)
Vegetables	Potatoes	MZ, MN, MT	1.6	11.2
Vegetables	Pumpkins	MN	1.6	12.8
Vegetables	Shallots	MZ, MN	2.4	24
Vegetables	**Squash (winter)** **Squash (summer)**	**MN** **MZ, MN**	**MZ = 2.4** **MN = 1.6**	**MZ = 19.2** **MN = 12.8**
Vegetables	Tomatoes	MZ, MN	2.4 (w), 1.6 (e)	6.4 (w), 16.8 (e)
Vegetables	Watermelons	MZ, MN	2.4	19.2

Note - Crops in bold have different rates depending upon which EBDC is used
(w) - West of the Mississippi River
(e) - East of Mississippi River

D. Estimated Usage of Pesticide

Approximately 5.6 million pounds of mancozeb are used annually. In terms of pounds applied, the greatest use is on potatoes and apples. In terms of percent crop treated, the greatest use is on potatoes (54 to 65% crop treated) and onions (50 to 65% crop treated). Mancozeb is also used extensively on apples, grapes, pears, tomatoes, and watermelons. Table 2 summarizes the best estimates of mancozeb usage currently available to the Agency.

Table 2. Mancozeb Crop Usage Summary

Crop	Pounds of Active Ingredient Used on Annual Basis	% Crop Treated	
		Weighted Average	Maximum
Apples	1,000,000	30	35
Asparagus	40,000	20	30
Green Beans	7,000	<1	5
Cabbage	8,000	5	10
Cantaloupes	20,000	5	10
Carrots	1,000	<1	<2.5
Field Corn	<500	<1	<2.5
Sweet Corn	100,000	10	15
Cotton	10,000	<1	<2.5
Cranberries	40,000	30	Not Available
Cucumbers	50,000	10	15
Eggplant	5,000	20	25
Garlic	20,000	10	40
Grapes	300,000	15	35
Onions	400,000	50	65
Nonbearing Citrus (nursery stock)	6,000	<1	<2.5
Peanuts	8,000	<1	<2.5
Pears	200,000	40	55
Peppers	20,000	5	10
Potatoes	2,900,000	54	65
Pumpkins	10,000	5	10

Crop	Pounds of Active Ingredient Used on Annual Basis	% Crop Treated	
		Weighted Average	Maximum
Squash	50,000	15	20
Sugar Beets	100,000	5	10
Tobacco	60,000	5	10
Tomatoes	600,000	25	50
Watermelons	300,000	35	45
Wheat	200,000	<1	<2.5

Weighted Average: the most recent years and more reliable data are weighted more heavily.

III. Summary of Mancozeb Risk Assessment

The following is a summary of EPA's human health and ecological risk assessments for mancozeb, as presented fully in the documents, *"Mancozeb. Health Effects Division (HED) Human Health Risk Assessment to Support Reregistration,"* dated June 3, 2005, *"ETU from EBDCs: Health Effects Division (HED) Human Health Risk Assessment of the Common Metabolite/Degradate ETU to Support Reregistration,"* dated June 8, 2005, *"Environmental Fate and Ecological Risk Assessment for Mancozeb, Section 4 Reregistration for Control of Fungal Diseases on Numerous Crops, a Forestry Use on Douglas Firs, Ornamental Plantings, and Turf (Phase 3 Response),"* dated June 22, 2005, and "*Environmental Fate and Ecological Risk Assessment for Ethylenethioureas (ETU) a Common Degradate of the Ethylenebisdithio-carbamate fungicides (EBDCs): Metiram, Mancozeb, and Maneb...(Phase 3 Response),"* dated June 21, 2005. Risks from ETU are considered in this RED because ETU is a common metabolite and degradate of mancozeb and the other EBDC fungicides. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments.

The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the safety finding and regulatory decision for mancozeb. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket OPP-2005-0176 and may also be accessed on the Agency's website at http://epa.gov/edockets. Hard copies of these documents may be found in the OPP public docket under this same docket number. The OPP public docket is located in Room 119, Crystal Mall II, 1801 South Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

EPA released its preliminary risk assessments for mancozeb for public comment on November 24, 2004 for a 90-day public comment period (Phase 3 of the public participation process). The preliminary risk assessments may be found in the OPP public docket at the address given above and in EPA's electronic docket under docket number OPP-2004-0078. In response to comments received and new studies submitted during Phase 3, the risk assessments were updated and refined. The human health risk assessment was revised again on June 3, 2005, to incorporate comments and additional studies submitted by the registrant. Revised risk assessments may be found in the OPP dockets under docket number OPP-2005-0176. Major revisions to the risk assessment include the following:

- Revision of the dietary exposure assessment to include updated usage information, new field trial and processing studies for some commodities, and a change in the toxicological endpoint used to assess acute dietary risk;
- Revision of the residential exposure assessment to reflect the pending deletion of mancozeb use on residential turf (Receipt of Request for Voluntary Cancellation published in *Federal Register* on June 1, 2005);
- Revision of post-application cancer risk estimates for golfers and other athletes to reflect incorporation of information on mancozeb usage on golf courses and athletic fields; and
- Revision of post-application risk estimates for cut flowers using new transfer coefficient.

This document summarizes risk estimates for both mancozeb and its metabolite and environmental degradate ethylene thiourea (ETU). Mancozeb and the other EBDC chemicals, maneb and metiram, are all metabolized to ETU in the body and all degrade to ETU in the environment. Therefore, EPA has considered the aggregate or combined risks from food, water and non-occupational exposure resulting from mancozeb alone, ETU resulting from mancozeb use, and ETU from all sources (including the other EBDC fungicides, maneb and metiram). The aggregate risk from ETU from all sources must be considered to reassess the tolerances for mancozeb *per se* and the other EBDCs, maneb and metiram, in accordance with FQPA.

1. Toxicity Summary for Mancozeb

Toxicity assessments are designed to predict whether a pesticide could cause adverse health effects in humans (including short-term or acute effects such as skin or eye damage, and lifetime or chronic effects such as cancer, development and reproduction deficiencies, etc.) and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for mancozeb and has determined that the toxicological database is sufficient for reregistration.

The toxicity database for mancozeb demonstrates that the thyroid is a target organ for mancozeb. Thyroid toxicity was manifested as alterations in thyroid hormones, increased thyroid weight, and microscopic thyroid lesions (mainly thyroid follicular cell hyperplasia), and thyroid tumors. A rat subchronic toxicity study showed microscopic neuropathology (injury to peripheral

nerves) with associated clinical signs (abnormal gait and limited use of rear legs) and loss of muscle mass.

Mancozeb is rapidly absorbed and eliminated in the urine. In oral rat metabolism studies with radiolabeled mancozeb and other EBDCs, the *in vivo* metabolic conversion of EBDC to ETU was 7.5% on a weight-to-weight basis. Although this metabolic conversion has been included in the mancozeb exposure and risk assessments, this metabolic conversion may not occur following dermal or inhalation exposure because the absorbed compound would initially bypass the liver, where metabolism occurs. Metabolism data indicate mancozeb does not bio-accumulate.

There is concern for developmental neurotoxicity resulting from exposure to mancozeb, due to the developmental effects observed following dosing with mancozeb and its metabolite ETU. Because the developmental effects are attributed to ETU, a developmental neurotoxicity study with ETU will be required.

For more details on the toxicity and carcinogenicity of mancozeb and ETU, see the *Mancozeb HED Toxicology Chapter for the Reregistration Eligibility Decision Document (RED)*, dated March 6, 2000, which is available at http://www.epa.gov/edockets under docket number OPP-2004-0078, and the memorandum, *Mancozeb, Toxicity Endpoints for Risk Assessment*, dated June 3, 2005, which is available in docket number OPP-2005-0176.

a. Acute Toxicity Profile

Available information on the acute toxicity of mancozeb is summarized in Table 3 below. The Agency used these acute toxicity values to set the interim restricted-entry intervals (REIs) on current pesticide labels in accordance with the Worker Protection Standard. These acute toxicity values are included in this document for informational purposes only. The studies upon which these values are based may or may not meet the current acceptance criteria. Mancozeb is not acutely toxic *via* the oral, dermal, or inhalation routes of exposure. Mancozeb causes eye irritation. Although animal data indicate that mancozeb is not a skin sensitizer (MRID 40469501), incident data and reports in the public literature indicate that skin sensitization may occur in humans. (See Section III.A.9.e. of this document for details.) The dermal sensitization study in animals is conducted on the manufacturing use product, whereas the reports of skin sensitization in humans are associated with end use products. The Agency requires additional product specific data on skin sensitization (and other acute effects) during product reregistration to determine appropriate product labeling.

Table 3. Acute Toxicity Data for Mancozeb.

Guideline No./ Study Type	MRID Number	Results	Toxicity Category
870.1100 Acute Oral Toxicity	00142522	LD50* > 5000 mg/kg	IV
870.1200 Acute Dermal Toxicity	00142522	LD50 > 5000 mg/kg	IV
870.1300 Acute Inhalation Toxicity	No Data	No Data Available	N/A
870.2400 Acute Eye Irritation	00142522	corneal damage < 7 days	III
870.2500 Acute Dermal Irritation	00142522	Negative	IV
870.2600 Skin Sensitization	40469501	Negative in animal study, reports of sensitization in humans	N/A

* LD50, Median Lethal Dose, statistically derived dose of a substance expected to cause death in 50% of test animals, expressed as weight of substance per weight of animal. N/A, not applicable.

b. FQPA Safety Factor Considerations for Mancozeb

FFDCA, as amended by the Food Quality Protection Act (FQPA), directs the Agency to use an additional tenfold (10X) special safety factor, to account for potential pre-and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrate the that the resulting level of exposure would be safe for infants and children.

Special FQPA Safety Factor. Studies available for FQPA consideration include acceptable developmental toxicity studies in rats and rabbits and an acceptable reproduction study in rats. These data showed no indication of increased susceptibility to fetuses or offspring. In the rat developmental study, developmental effects were observed in the presence of severe maternal effects, including maternal mortality and clinical signs. In the rabbit developmental study, developmental effects (spontaneous abortions) were observed at the same dose (80 mg/kg/day) at which maternal effects included mortality and clinical signs. In the rat reproduction study, no effects were observed in offspring, while thyroid effects and body weight gain decrements occurred in adults. Therefore, the Agency reduced the Special FQPA Safety Factor to 1X due to the lack of evidence of pre- and/or postnatal susceptibility resulting from exposure to mancozeb and the lack of residual uncertainties.

Database Uncertainty Factor. No additional uncertainty factors were deemed necessary for mancozeb to account for uncertainties in the toxicology database. Although there is a data gap for an acute neurotoxicity study with mancozeb, a No Observable Adverse Effect Level (NOAEL) from this study is expected to be greater than the acute dietary endpoint because the NOAEL for the acute neurotoxicity study with maneb was 1000 mg/kg/day.

c. Toxicological Endpoints for Mancozeb

The toxicological endpoints used in the human health risk assessment for mancozeb are listed in Table 4. Safety factors used to account for interspecies extrapolation, intraspecies

variability, special susceptibility to infants and children, and any additional database uncertainties are also described in Table 4. This table also provides absorption factors used to extrapolate from a study conducted by one route of exposure to (e.g., oral) to human exposure occurring by a different route (e.g., dermal). EPA used chemical specific data to derive these absorption factors. Toxicological endpoints for ETU are described later in this document.

Table 4. Toxicological Endpoints for Mancozeb Human Health Risk Assessment

Exposure Scenario	Dose, Uncertainty Factors, and Safety Factors	Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)	Study and Toxicological Effects
Mancozeb Dietary Exposures			
Acute Dietary Females age 13-49	NOAEL = 128 mg/kg/day UF=100X (inter and intraspecies) FQPA SF=1X Total UF=100X Acute RfD = 1.3 mg/kg/day	aPAD = $\frac{\text{Acute RfD}}{\text{FQPA SF}}$ aPAD = 1.3 mg/kg/day	Developmental Toxicity, rat LOAEL = 512 mg/kg/day based on hydrocephaly and other malformations
Acute Dietary General Population	N/A	No appropriate endpoint was identified from oral toxicity studies.	
Chronic Dietary General Population	NOAEL= 4.83 mg/kg/day UF=100X (inter and intraspecies) FQPA SF=1X Total UF=100X Chronic RfD=0.05 mg/kg/day	cPAD = $\frac{\text{Chronic RfD}}{\text{FQPA SF}}$ cPAD = 0.05 mg/kg/day	Toxicity/Carcinogenicity, rat LOAEL = 30.9 mg/kg/day based on thyroid toxicity.
Mancozeb Incidental Oral Exposures			
Any Duration [1 day to 6 mos.]	NOAEL = 9.24 mg/kg/day UF=100X (inter and intraspecies) FQPA SF=1X Total UF=100X	Residential MOE=100	Subchronic toxicity, rat LOAEL = 17.82 mg/kg/day based on decreased thyroxine.
Mancozeb Dermal Exposures			
Short-Term [1-30 days] and Intermediate-Term [>30 days to 6 mos.]	None	Not Applicable. No systemic toxicity noted via the dermal route at 1000 mg/kg/day and there are no developmental concerns at systemic doses likely to occur as a result of dermal exposures from registered uses.	
Long-Term [> 6 months]	NOAEL = 4.83 mg/kg/day UF=100X (inter and intraspecies) FQPA SF=1X Dermal absorption = 1%	Residential MOE=100 Occupational MOE=100	Toxicity/Carcinogenicity, rat LOAEL = 30.9 mg/kg/day based on thyroid toxicity.

Exposure Scenario	Dose, Uncertainty Factors, and Safety Factors	Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)	Study and Toxicological Effects
Mancozeb Inhalation Exposures			
Any Duration [1day to > 6 mos.]	NOAEL = 0.079 mg/L [equivalent to 21 mg/kg/day] UF=100X (inter and intraspecies) FQPA SF=1X	Residential MOE=100 Occupational MOE=100	Subchronic Inhalation, rat LOAEL = 0.326 mg/L based on thyroid hyperplasia and decreased thyroxine (females)
NOAEL- No Observable Adverse Effect Level, the highest dose at which no adverse health effect is observed. **LOAEL** - Lowest Observable Adverse Effect Level, the lowest dose at which an adverse health effect is observed. **aPAD/cPAD** - acute and chronic, respectively, population adjusted dose (PAD), a reference dose which has been adjusted to account for the FQPA safety factor. **Dermal absorption factor** based on chemical specific data.			

2. Toxicity Summary for ETU

As previously mentioned, some of the toxicity of the parent EBDCs is attributed to their common metabolite, ETU. The toxicology database for ETU contains a limited number of FIFRA guideline studies; therefore, the Agency has relied on a combination of literature studies and unpublished studies conducted according to the OPPTS testing guidelines. The thyroid is a target organ for ETU, and thyroid toxicity as a result of ETU exposure has been noted in subchronic and chronic rat, mouse, and dog studies. Overt liver toxicity was observed in one chronic dog study. Developmental defects in the rat developmental study included hydrocephaly and related lesions, skeletal system defects, and other gross defects. These effects showed increased susceptibility to fetuses because they occurred at a dose associated only with decreased maternal food consumption and body weight gain but not with significant maternal toxicity. For more details on the toxicity and carcinogenicity of ETU see the document, *"ETU-3rd Report of the Hazard Identification Assessment Review Committee,"* dated May 28, 2003.

a. Acute Toxicity Profile of ETU

ETU demonstrates low acute toxicity via dermal (Toxicity Category III) and inhalation (Toxicity Category IV) routes of exposure. Because ETU is not irritating to the eyes or the skin, it is in Toxicity Category IV for both Primary Eye Irritation and Primary Skin Irritation. However, acute oral and dermal sensitization studies with ETU were not available to determine acute toxicity. The acute toxicity profile for ETU is summarized in Table 6 below.

Table 6. Acute Toxicity of ETU

Guideline No.	Study Type	MRID No.	Results	Toxicity Category
870.1100	Acute Oral - rat	None	N/A	N/A
870.1200	Acute Dermal - rabbit	45888101	LD_{50} > 2000 mg/kg	III
870.1300	Acute Inhalation - rat	45888102	LC_{50} > 10.4 mg/L	IV

870.2400	Primary Eye Irritation	45888104	No irritation	IV
870.2500	Primary Skin Irritation	45888103	No irritation	IV
870.2600	Dermal Sensitization	None	N/A	N/A

b. FQPA Safety Factor Consideration for ETU

FQPA Special Safety Factor. Because of evidence of increased susceptibility of fetuses following exposure to ETU in the rat developmental studies, the Agency evaluated the level of concern for the effects observed when considered in the context of all available toxicity data. In addition, the Agency evaluated the database to determine if there were residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the ETU risk assessment. The Agency determined that the degree of concern for the susceptibility seen in ETU developmental studies was low for the following reasons:

- The teratogenic effects have been well-characterized in numerous studies in the published literature, as well as in a guideline study submitted by the registrant;
- There is a clear NOAEL for these effects and the dose-response relationship, although steep, is well characterized in the numerous developmental studies in rats.
- The developmental endpoint with the lowest NOAEL was selected for deriving the acute RfD.
- The target organ toxicity (thyroid toxicity) was selected for deriving the chronic RfD as well as endpoints for non-dietary exposures (incidental oral, dermal, and inhalation).

Because the ETU doses selected for overall risk assessments will address the concern for developmental and thyroid toxicity, there are no residual uncertainties with regard to pre- and/or post-natal toxicity. The Agency concluded that the Special FQPA Safety Factor (SF) could be removed (reduced to 1X) for ETU.

FQPA Database Uncertainty Factor. The Agency concluded that a developmental neurotoxicity study for ETU is required, based on severe central nervous system defects observed in the developmental toxicity study in rats. In addition to the developmental neurotoxicity study, the following data gaps were identified:

- Developmental toxicity study in rabbits
- 2-Generation reproduction study in rats
- Comparative thyroid toxicity study in adults and offspring.

The Agency determined that a 10x database uncertainty factor (FQPA UF_{DB}) must be retained to account for the lack of these studies.

c. Toxicological Endpoints for ETU

The toxicological endpoints used in the human health risk assessment for ETU are listed in Table 7 below, together with safety factors used to account for interspecies extrapolation, intraspecies variability, the potential for special susceptibility to infants and children (FQPA 10X), and database uncertainties related to FQPA safety factor considerations. Table 7 also provides dermal absorption factors used to extrapolate from oral studies to dermal exposure.

Table 7. ETU Toxicological Endpoints for Use in Human Health Risk Assessment

Exposure Scenario	Dose, Uncertainty Factors, and Safety Factors	PAD or Target MOE	Study and Toxicological Effects
ETU Dietary Exposures			
Acute Dietary Females 13 - 49	NOAEL = 5 mg/kg/day UF = 100X (inter and intraspecies) FQPA SF = 1X FQPA UF_{DB} = 10X Total UF = 1000X Acute RfD = 0.005 mg/kg/day	aPAD = $\frac{\text{Acute RfD}}{\text{FQPA SF}}$ aPAD = 0.005 mg/kg/day	Developmental Rat Toxicity (Khera Study, MRID 459376-01) LOAEL = 10 mg/kg/day, based on developmental defects in the brain.
Acute Dietary General Population	Not Applicable	No appropriate endpoint attributable to a single exposure (dose) was identified.	
Chronic Dietary	NOAEL = 0.18 mg/kg/day UF=100X (inter and intraspecies) FQPA SF = 1X FQPA UF_{DB} = 10X Chronic RfD=0.0002 mg/kg/day	cPAD = $\frac{\text{Chronic RfD}}{\text{FQPA SF}}$ cPAD = 0.0002 mg/kg/day	Dog Chronic Oral Toxicity (MRID 42338101) LOAEL= 1.99 mg/kg/day based on thyroid toxicity
ETU Incidental Oral or Dermal Exposures [Toddler and Youth Post-Application]			
Short-Term [1-30 days] Intermediate-Term [>30 days to 6 months]	NOAEL = 7 mg/kg/day UF = 100X (inter and intraspecies) FQPA UF_{DB} = 10X FQPA SF = 1X Dermal Absorption = 26%	Residential MOE = 1000	4-week range-finding dog study LOAEL= 34 mg/kg/day based thyroid toxicity
ETU Dermal Exposures			
Short-Term [1-30 days] Females 13-49 Intermediate-Term [30 days - 6 months]	NOAEL = 5 mg/kg/day UF = 100X (inter and intraspecies) FQPA UF_{DB} = 10X FQPA SF = 1X Dermal Absorption = 26%	Residential MOE = 1000 Occupational MOE = 100	Same as above for acute dietary exposures.

Exposure Scenario	Dose, Uncertainty Factors, and Safety Factors	PAD or Target MOE	Study and Toxicological Effects
Long-Term [> 6 months]	NOAEL = 0.18 mg/kg/day UF = 100X (inter and intraspecies) FQPA SF = 1X FQPA UF_{DB} = 10X Dermal Absorption = 26%	Occupational MOE = 100	Same as above for chronic dietary exposures.
ETU Inhalation Exposures			
Short-Term [1-30 days] Females 13-49 Intermediate-Term [30 days - 6 months]	NOAEL = 5 mg/kg/day UF = 100X (inter and intraspecies) FQPA UF_{DB} = 10X Inhalation Absorption = 100%	Residential MOE = 1000 Occupational MOE = 100	Same as above for acute dietary exposures.
Long-Term [>6 months]	NOAEL = 0.18 mg/kg/day UF = 100X (inter and intraspecies) FQPA SF =1X FQPA UF_{DB} = 10X Inhalation Absorption = 100%	Occupational MOE = 100	Same as above for chronic dietary exposures.
NOAEL- No Observable Adverse Effect Level, the highest dose at which no adverse health effect is observed. **LOAEL** - Lowest Observable Adverse Effect Level, the lowest dose at which an adverse health effect is observed. **aPAD/cPAD** - acute and chronic, respectively, population adjusted dose (PAD), a reference dose which has been adjusted to account for the FQPA safety factor. **Dermal absorption factor** is based on chemical specific data.			

3. Carcinogenicity of Mancozeb and ETU

In assessing the carcinogenicity of pesticides, the Agency first evaluates evidence that the pesticide is a carcinogen. If there is evidence, such as tumor formation, and the pesticide is classified as a carcinogen, a quantitative assessment is conducted using a Q_1* (non-threshold) or a Margin of Exposure (threshold) approach. The mechanism of tumor formation determines whether or not a threshold or non-threshold assessment is conducted.

In a combined chronic/carcinogenity study on mancozeb in rats, thyroid follicular cell adenomas and carcinomas were increased in high-dose males and females. This study also showed changes in thyroid hormone levels, increased thyroid weight, and microscopic pathology of the thyroid. The Agency deemed dosing in this study adequate to assess carcinogenicity of mancozeb. A mouse study was also conducted, showing minor changes in thyroid hormone levels but no changes in thyroid weight or pathology, and no treatment-related changes in tumor rates. Therefore, doses in the mouse study were deemed too low to assess carcinogenicity. In 1992, EPA reviewed the mancozeb database relevant to carcinogenicity and classified mancozeb as a group B2 probable human carcinogen.

Because mancozeb is degraded and/or metabolized to ethylene thiourea (ETU) which causes the same types of thyroid tumors, EPA has historically attributed mancozeb's carcinogenicity to the formation of ETU, which is classified as a probable human carcinogen (B2). The Agency has used the cancer potency factor (Q_1^*) of 0.0601 $(mg/kg/day)^{-1}$ for ETU (based on liver tumors in female mice) for risk assessment. Therefore, cancer risk from exposure to mancozeb has been calculated by estimating exposure to mancozeb-derived ETU and using the Q_1* for ETU. The same approach has been taken for the other EBDCs. EPA's estimated exposure to mancozeb-derived ETU included ETU formed by metabolic conversion in the body (conversion rate of 0.075). In a 1999 review, the Agency re-affirmed this approach to cancer risk assessment for the EBDCs.

Table 5. Tumor Incidence in EBDC/ETU Carcinogenicity Studies in Rats and Mice

Species	ETU	Mancozeb	Maneb	Metiram
Rats	Thyroid follicular cell adenomas and carcinomas at 83 & 250 pPE	Thyroid follicular cell adenomas and carcinomas at 750 pPE (HDT) [56 pPE ETU]	No increase in tumor of any type at 1000 pPE (HDT) [75 pPE ETU]	No increase in tumor of any type at 320 pPE (HDT) [24 pPE ETU]
Mice	Thyroid follicular cell adenomas and carcinomas, pituitary adenomas, hepatocellular adenomas and carcinomas at 1000 pPE	No increase in tumor of any type at 1000 pPE (HDT) [75 pPE ETU]	Increase incidence of hepatocellular adenomas and alveogenic adenomas in the lungs at 2400 pPE [180 pPE ETU]	No increase in tumor of any type at 1000 pPE [75 pPE ETU]

HDT - Highest Dose Tested. [ ] Numbers in brackets represent the dose level in ETU equivalents based on a 7.5% conversion of parent EBDC to ETU

4. Endocrine Effects of Mancozeb and ETU

The available human health and ecological effects data for mancozeb suggest possible endocrine effects. Mammalian studies for mancozeb showed thyroid effects, which may indicate potential endocrine disruption. EPA has considered these effects in the human health risk assessment by selecting endpoints based on thyroid effects. To further characterize these effects, EPA is requiring a confirmatory comparative thyroid toxicity study for ETU. Mancozeb data on ecological effects suggest possible hormonal effects to birds and mammals. These effects will be addressed when the Agency's Endocrine Disruptor Screening and Testing Advisory Committee develops appropriate screening and/or testing protocols. At that time, mancozeb and/or ETU may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

5. Dietary Exposure and Risk from Food

a. Exposure Assumptions

EPA conducted acute, chronic and cancer dietary (food) risk assessments for mancozeb and its metabolite ETU using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96 and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Reported food consumption is linked to EPA-defined food commodities using publicly available recipe translation files developed jointly by EPA and USDA's Agricultural Research Service. These consumption data are averaged for the entire U.S. population and within population subgroups for chronic and cancer exposure assessment, but are retained as individual consumption events for acute exposure assessment.

The acute and chronic dietary (food) risk analyses were conducted using anticipated residue values from field trial and market basket survey data. The 1989-1990 market basket survey for EBDCs and ETU was the largest of its kind with 6000 samples (300 samples for each of 10 crops and food forms). Processing factors, cooking factors, and estimated percent crop treated information were also incorporated into the dietary risk assessment.

The Agency derived anticipated residues for ETU from market basket survey data, ETU formed from mancozeb during processing, and ETU formed by metabolic conversion of mancozeb. Because ETU is both a metabolite and environmental degradate of mancozeb and the other two EBDC fungicides, it was considered in the dietary risk assessment.

b. Population Adjusted Dose

The Population Adjusted Dose (PAD) characterizes the dietary risk of a chemical (from residues in food), and reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA SF. Estimated dietary (food) risks less than 100% of the Population Adjusted Dose (PAD), either acute (aPAD) or chronic (cPAD), are not of concern to the Agency. The PAD is the dose predicted to result in no unreasonable health effects to any human subpopulation, including sensitive members of such subpopulations. The aPAD is the dose at which a person could be exposed on any given day, and the cPAD is the dose at which a person could be exposed over the course of a lifetime, with no expected adverse health effects. Because the Special FQPA SF has been removed for mancozeb, and there is no database uncertainty factor for FQPA concerns, the acute or chronic RfD is identical to the respective aPAD or cPAD.

Acute dietary analyses were conducted for the population subgroup females 13-49 years old, the only relevant population subgroup given the endpoint selected from the available toxicity studies. Chronic dietary analyses were conducted for the general U.S. population and various population subgroups.

Acute Risk from Food. The Agency conducted a highly refined, probabilistic acute dietary assessment using a distribution of residue data for nonblended and partially blended commodities. For mancozeb, the acute dietary risk from food at the 99.9th percentile was < 1% of the aPAD for females age 13-49 years, the only relevant subpopulation. For ETU, the acute dietary risk from food at the 99.9th percentile was 18% of the aPAD for females age 13-49 years for mancozeb-derived ETU and 55% for ETU from all sources. Therefore, EPA does not have an acute risk concern for residues of either mancozeb or ETU in food.

Chronic Risk from Food. Chronic (non-cancer) dietary risk from food is calculated by using the average consumption value for foods and average residue values on those foods over a 70-year lifetime. The chronic assessment used deterministic methodology to provide point estimates of risk. Chronic dietary risk values for mancozeb, mancozeb-derived ETU, and ETU from all sources are presented in Table 8. The chronic dietary risk from food alone is below EPA's level of concern. For both mancozeb and ETU, chronic dietary exposure from food comprises less than 100% of the chronic PAD for the US population and all subpopulations.

Table 8. Summary of Chronic Dietary Risk for Mancozeb and ETU

Population Subgroup	Mancozeb %cPAD	ETU % cPAD	
		Mancozeb-derived ETU	ETU from all Sources
General U.S. Population	<1	9	16
All Infants (< 1 year old)	<1	14	31
Children 1-2 years old	<1	30	54
Children 3-5 years old	<1	23	36
Children 6-12 years old	<1	13	16

Note: cPAD is 0.05 and 0.0002 mg/kg/day for mancozeb and ETU, respectively.

c. Cancer Risk

The cancer dietary risk assessment was conducted for the general U.S. population. To estimate cancer risk, the lifetime average daily exposure is multiplied by the cancer potency factor (Q_1^*) to yield a unitless risk number which represents the number of excess cancers potentially attributed to consumption of the pesticide over a lifetime. For the cancer dietary (food) risk assessment, risk estimates within the range of an increased cancer risk of one in one million (1×10^{-6}) are below EPA's level of concern.

As previously mentioned, the Agency's cancer concern for mancozeb is limited to risk from ETU. The estimated lifetime dietary exposure to ETU derived from mancozeb corresponds to a cancer risk estimate of 1×10^{-6}. Cereal grains, mango, and milk are the major contributors to dietary risk from mancozeb-derived ETU. The estimated lifetime dietary exposure to ETU from all sources corresponds to a cancer risk estimate of 2×10^{-6}, which is within the negligible risk range of 10^{-6} and not considered to be of concern. Leaf lettuce and apple juice are the major contributors to the cancer dietary risk estimate for ETU from all sources.

6. Dietary Exposure from Drinking Water

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling and/or monitoring data, if the latter is available and of sufficient quality, to estimate those exposures. Risks from exposure to ETU in drinking water are further discussed in the section titled "Aggregate Exposure and Risk."

The Agency prepared a drinking water exposure assessment for ETU only. The parent EBDC fungicides were not assessed because they are very short-lived in soil and water, and are not expected to reach water used for human consumption, whether from surface water or groundwater sources. ETU, however, is highly water soluble, and moderately mobile, and may reach both surface and groundwater under some conditions. ETU has an aerobic soil half-life of about 3 days; in the absence of data, the aerobic aquatic metabolism half-life was assumed to be about 6 days, or double the soil half-life. The measured anaerobic aquatic metabolism half-life, however, is substantially longer (149 days), which may lead to the periodic detections in groundwater. The ETU estimated drinking water concentrations (EDWCs) were generated using data from both monitoring and modeling. Table 9 shows the EDWCs used to assess exposure to ETU in drinking water from surface water and groundwater sources.

Table 9. Estimated Drinking Water Concentrations (EDWC) for ETU

Drinking water source	Duration	EDWC (ppb)	Data Source
Surface Water	Acute (Peak)	25.2	Modeling
	Chronic/Cancer	0.1	Monitoring
Groundwater	All Durations	0.21	Monitoring

a. Surface Water

Monitoring data for ETU from a targeted surface water monitoring study conducted by the ETU Task Force were available for use in the risk assessment. In the study, none of the tested surface water samples had concentrations above the limit of detection of 0.1 ppb. Therefore, the chronic/cancer EDWC was assigned the value of 0.1 ppb of ETU. The monitoring value of 0.1 ppb of ETU was also assigned to be the lower limit of the acute EDWC. In addition, the Agency decided that a higher limit for the acute value is necessary because monitoring samples were taken every 14 days during the application season and peak values may have been missed. To obtain this value, the Agency performed PRZM/EXAMS simulation modeling for 22 crop scenarios. In modeling, the Agency considered the use patterns for all of the EBDCs and chose the highest application rate and lowest application intervals. Modeling results showed the highest one-in-ten year acute surface water EDWC to be 25.2 ppb based on application of EBDCs to peppers crop in Florida. Therefore, a range of acute EDWCs was established with a lower limit, based on monitoring and an upper limit based on the PRZM/EXAMS modeling described above. The established range of acute Estimated Drinking Water Concentration (EDWC) values for surface water, at the national level, is expected to be between the detection limit of 0.1 ppb (from monitoring) and the highest peak value 25.2 ppb (from modeling after adjustment by the 0.87

national percent crop area factor or PCA). In summary, the Agency used a combined approach to assess drinking water exposure using both targeted surface water monitoring and simulation modeling to bracket the expected acute concentrations of ETU in drinking water between 0.1 and 25.2 ppb. Chronic surface water values were set conservatively at 0.1 ppb, the detection limit for the monitoring data.

b. Groundwater

A groundwater EDWC was selected from a targeted monitoring study conducted in 2001 to 2003 in seven states chosen to represent the high historic use areas in the US. Based on the monitoring results, the highest measured value in a public drinking water well was 0.210 ppb in Lee County, Florida. Therefore, the groundwater EDWC is assigned the value of 0.21 ppb of ETU. In this study, ETU was not detected in any of the treated community drinking water sampled from the monitored 84 sites even when it was detected in the raw water. The absence of ETU in potable water from community water supplies may be related to its rapid degradation resulting from aeration and chemical treatment.

7. Residential and Other Nonoccupational Risk

Residential and nonoccupational exposure assessments consider all potential nonoccupational pesticide exposure, other than exposure due to residues in foods or in drinking water. Residential exposures to mancozeb and mancozeb-derived ETU are likely to occur based on registered uses. Products containing mancozeb are intended for use on home vegetable gardens and ornamentals. Therefore, EPA evaluated exposures to residential handlers who apply these products, and to adults and youth who re-enter gardens to harvest crops (post-application).

Mancozeb is also registered for use on turf, including sod farms, golf courses, and athletic fields. Therefore, EPA has considered the potential post-application exposure to golfers, athletes, and toddlers from use of mancozeb on golf course turf, athletic fields, and transplanted lawns, respectively. As a result, risk assessments have been completed for both residential handler and post-application scenarios, including handler exposure from application of mancozeb to ornamentals and home gardens, exposure to golfers and athletes from treated turf on golf courses and athletic fields, and exposure to toddlers who might be playing on transplanted turf previously treated with mancozeb.

Some mancozeb labels have permitted use on residential turf when mancozeb is applied by professional lawn care operators. However, registrants are voluntarily amending all mancozeb labels to delete use of mancozeb on residential turf, and a formal *Notice* of this action was published in the *Federal Register* on June 1, 2005 (Vol. 70, No. 104, pp. 31447-31450). The Agency intends to issue a cancellation order for the residential turf use. Therefore, this use was not included in the residential risk assessment for this RED.

The Agency has evaluated residential handler exposure from mixing/loading/applying mancozeb to home gardens and post-application exposure to adults and children from contact with treated turf and hand to mouth transfer. All of these scenarios are considered to be short-term in

nature due to episodic use. Therefore, EPA limited the risk assessment for mancozeb *per se* to inhalation exposure (handlers) and post-application incidental oral exposure because no significant toxicity for mancozeb *per se* was noted by the dermal route of exposure. For mancozeb-derived ETU and ETU from all sources, the Agency evaluated dermal and inhalation exposure for homeowner handlers and dermal and incidental oral exposure for post-application exposure.

Because no chemical-specific data were available to assess the residential exposure scenarios listed above, the Agency used surrogate data from the Pesticide Handlers Exposure Database (PHED, Version 1.1 August 1998), which is used to assess handler exposures when chemical-specific monitoring data are not available. In addition to PHED data, this risk assessment also relies on data from the Outdoor Residential Exposure Task Force (ORETF) and proprietary studies. For more information, see the Agency document, *"Mancozeb: 2nd Revised Occupational and Residential Exposure Assessment and recommendations for the Reregistration Eligibility Decision Document,"* dated May 31, 2005.

a. Risk Estimates for Homeowner Handlers

To estimate residential risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the NOAEL selected for risk assessment to the exposure. This MOE is compared to a level of concern, which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. The standard UF is 100X (10X for interspecies extrapolation and 10X intraspecies variation), plus any additional safety factors, such as an FQPA safety factor or database uncertainty factor. An MOE less than the target MOE, or level of concern, is generally a risk concern to the Agency. As previously mentioned in this document, the Special FQPA Safety Factor for mancozeb has been reduced to 1X, so that the total uncertainty factor for mancozeb is 100X (Table 4). For ETU, the Special FQPA Safety Factor has been reduced to 1X but a 10X Database UF has been added to account for lack of toxicity data on certain areas of concern (Table 7). Therefore, the Agency's level of concern is an MOE of 100 for mancozeb and an MOE of 1000 for ETU.

The Agency evaluated risks to homeowner handlers applying products containing mancozeb to ornamentals and home vegetable gardens. EPA does not have risk concerns for homeowner handlers. Short- and intermediate-term MOEs are >110,000 and well above the Agency's targets for both mancozeb and ETU. Cancer risks are well below 1×10^{-6}. A summary of mancozeb and ETU handler risk for home owners is provided below in Table 10.

Table 10. Home Gardener Handler Risks for Mancozeb and ETU

Exposure Scenario	Appl. Rate (lb ai/A)	Area Treated	Inhalation MOE for Mancozeb	Short-Intermediate Term MOE for ETU	ETU Cancer Risk
Backpack Sprayer	2.4	1000 ft^2	8.9×10^5	6.2×10^5	4×10^{-9}
Low Pressure Handwand			3.0×10^6	1.10×10^5	2×10^{-8}

b. Post-Application Residential Risks

Post-application risks for harvesting activities are below EPA's level of concern for ETU (i.e., MOEs > 1000 and cancer risk < 1 x 10^{-6}). The post-application exposure estimates for curcurbits were used instead of sweet corn because there is minimal use of mancozeb on sweet corn in home gardens. A post-application assessment was not conducted for mancozeb because no effects were observed at the limit dose in the 28 day dermal toxicity study. Cancer risks were calculated for adults only, and were all below 1.6 x 10^{-7}, the risk associated with hand harvesting cucurbits on the day of application. A summary of post-application exposure and risk is provided in Table 11 below.

Table 11. Home Gardener Post-Application Risks for Mancozeb-Derived ETU

Exposure Scenario	Non Cancer MOE for ETU	ETU Cancer Risk, Adults only
Youth	29000	Not Applicable
Adults	16000	1.6 x 10^{-7}

EPA assessed post-application risks to toddlers on turf by assuming that sod would be installed in a residential setting no sooner than three days after mancozeb application. (Registrants have agreed to a 3-day prohibition on harvesting following mancozeb application.) The total MOE for mancozeb is 93 and slightly below the target MOE of 100 when harvesting occurs one day after treatment. The total MOE for mancozeb rises to 100 with a 2 day harvesting prohibition while the total MOE for ETU rises to 1000 with a 3 day harvesting prohibition. Post-application risk estimates for toddlers are summarized in Table 12.

Table 12. Post-Application Risks for Toddlers Exposed to Turf

Exposure Pathway	Mancozeb		Mancozeb-Derived ETU	
	MOE with current 24 h REI	Prohibition on Harvesting (days) Needed to Reach an MOE of 100	MOE with current 24 h REI	Prohibition on Harvesting (days) Needed to Reach an MOE of 1000
Dermal	N/A	N/A	1400	1
Hand-to-Mouth	110	1	1100	1
Object-to-Mouth	460	0	4300	0
Soil Ingestion	34000	0	320000	0
Total*	93	2	530	3

* Total MOE is the sum of the reciprocals of the dermal, hand-to-mouth, object-to-mouth, and soil ingestion MOEs. Dermal exposure is only relevant to ETU because dermal toxicity data for mancozeb show no toxicological effects.

The MOEs and cancer risks for the golfer and athlete turf scenarios are summarized in Table 13. The MOEs were calculated using day zero turf transferrable residue (TTR) for short-term exposures and the cancer risk was calculated using seven day average TTR for lifetime exposures. Although the MOE for golfers exceeds the target MOE of 1000, the MOE for athletes

(450) is below the target MOE and of concern. To address this risk concern, the mancozeb registrants have requested that the use on athletic fields be cancelled.

The cancer risk for golfers is 6×10^{-9}, assuming that golfers play an average of 19 days per year and 50 years over a lifetime. In addition, the cancer risk value is adjusted to account for the amount of mancozeb used. Data from the National Golf Federation indicate that golfers play an average of 19 days per year and mancozeb use data indicate that mancozeb is applied to 20% of all US golf courses, with 6 applications per year.

The cancer risk for athletes is 6×10^{-8}, assuming 10 days of exposure per year and 10 years exposure per lifetime, with an adjustment for the usage of mancozeb on athletic fields (only 1% of all athletic fields are treated). Because the cancer risks for golfers and athletes are both less than 1×10^{-6}, the Agency does not have a cancer risk concern.

Table 13. Post-Application Risks for Adults Exposed to Turf (Mancozeb-derived ETU)

Exposure Scenario	Days per Year Exposure	Years Exposure per Lifetime	ETU Short-/Intermediate-Term MOE	ETU Cancer Risk Estimate
Golfing	1	50	6600	6.0×10^{-9}
Athletics	1	10	450	6.0×10^{-8}

8. Aggregate Exposure and Risk

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require the Agency to determine "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. When aggregating exposure and risk from various sources, the Agency considers the route and duration of exposure.

As previously mentioned, mancozeb and the other EBDC chemicals, maneb and metiram, are all metabolized to ETU in the body and all degrade to ETU in the environment. Therefore, EPA has conducted aggregate risk assessments for food, drinking water, and non-occupational exposure resulting from mancozeb alone; ETU resulting from mancozeb use (mancozeb-derived ETU); and ETU from all sources (including the other EBDC fungicides, maneb and metiram). EPA has conducted acute, short-term, and chronic (cancer and non-cancer) aggregate risk assessments.

The Agency's Phase 3 aggregate risk assessment indicated risks above levels of concern for toddler exposure to transplanted turf treated with maneb and mancozeb. Recognizing that potential risk, the maneb and mancozeb registrants agreed to reduce the maximum application rate and/or extend the time between treatment and harvesting of sod from one to three days. In addition, the minimum time that would elapse between treatment and installation of sod in a residential setting would be within the range of four to six days, given the typical one to three day

installation window following harvesting. Further, EPA expects the frequent and long duration of watering of newly installed sod and the need to restrict foot traffic for several weeks after planting to also minimize children's exposure to residues on transplanted turf. The reduced application rate and/or extended PHI, combined with the logistics of transplanting turf and installation restrictions, effectively reduced the potential contribution from this use pattern to a level not of concern to the Agency. The Agency has determined that quantitative estimation of aggregate risk for transplanted turf exposure scenarios is not necessary due to these factors and because such exposures are expected to be rare events.

Exposure to mancozeb *per se* is not expected from the water pathway, so aggregate exposure and risk for mancozeb *per se* are limited to combined food and residential pathways. Also, because mancozeb does not show dermal toxicity and because inhalation exposure is not expected to occur during residential post-application exposure, EPA did not include a residential post-application scenario in the aggregate assessment for mancozeb. Therefore, the only aggregate risk assessment conducted for mancozeb per se was for potential short-term handler exposures, from home garden use (food + residential).

Aggregate risks for ETU include food, drinking water, residential, and recreational exposure (i.e., golfing). The ETU aggregate includes assessments for mancozeb-derived ETU and for ETU from all sources where appropriate. Mancozeb and maneb are both currently registered for use on golf courses, and these uses result in post-application exposure to adults while golfing. Mancozeb is also used on athletic fields, resulting in post-application exposure to adults playing sports on treated turf; however, registrants have requested that this use be deleted. Mancozeb is the only EBDC fungicide which may be used in home gardens; therefore, only mancozeb-derived ETU is included in the residential portion of the aggregate exposure. Aggregate risk assessment scenarios considered for ETU are listed in Table 14 below.

Table 14. Summary of Data Sources for ETU Aggregate Risk Assessments

Aggregate Scenario	Mancozeb-derived ETU		ETU from All Sources*	
Data Source	Food & Water	Residential*	Food & Water	Residential*
acute (food + water)	✓		✓	
non-cancer chronic (food + water)	✓		✓	
cancer (food + water)	✓		✓	
short-term residential handler (food + water + residential)	✓	✓	✓	
short-term post-application, home garden (food + water + residential)	✓	✓	✓	
short-term post-application, golfing (food + water + residential)	✓	✓	✓	✓
cancer handler, home garden (food + water + residential)	✓	✓	✓	

Aggregate Scenario	Mancozeb-derived ETU		ETU from All Sources*	
cancer post-application, home garden (food + water + residential)	✓	✓	✓	
cancer post-application, golfing (food + water + residential)	✓	✓	✓	✓

* Only mancozeb-derived ETU was considered in aggregate exposure scenarios that include a residential exposure component because mancozeb is the only EBDC fungicide with home garden uses. Because both maneb and mancozeb are used on turf, golfers may be exposed to ETU from both sources.

The Agency used two approaches to calculating aggregate risk from food and water, depending on the scenario. A drinking water level of comparison (DWLOC) approach was used for mancozeb-derived ETU. EPA calculated a DWLOC, which represents the maximum allowable exposure through drinking water after considering food and residential exposures. If the EDWCs are less than the DWLOCs, EPA does not have concern for aggregate exposure or risk. If EDWCs are greater than DWLOCs, EPA will conduct further analysis to characterize the potential for aggregate risk of concern. The aggregate risk assessment for ETU from all sources used a semi-probabilistic approach for the acute assessment, adding the point estimate for ETU in drinking water (25.2 ppb) to the full range of food residue data using the DEEM-FCID model. For ETU from all sources, aggregate risk was expressed as %aPAD or %cPAD.

a. Mancozeb Aggregate Risk

The Agency considered short-term aggregate risk for mancozeb for residential handlers using mancozeb in home gardens. This assessment includes dietary exposure from food and inhalation exposure to residential handlers. EPA considers exposure to residential handlers to be short term, due to the intermittent and seasonal nature of pesticide use in home gardens. Handler inhalation risk was aggregated with dietary risk for the general population. Aggregate MOEs are significantly higher than the target MOE of 100 and are therefore not of concern (Table 15).

Table 15. Mancozeb Short-Term Aggregate Handler Risk, Home Garden.

Exposure Scenario	Residential Handler Absorbed Dose (mg/kg/day)	MOE	Dietary (Food) Exposure (mg/kg/day)	MOE	Aggregate MOE
Backpack Sprayer	2.4×10^{-5}	880000	0.000043	210000	170000
Low Pressure Handwand	7.1×10^{-6}	3000000			200000
Aggregate MOE = $\frac{1}{1/MOE_{handler} + 1/MOE_{food}}$					

b. ETU Aggregate Risk

As previously mentioned, EPA conducted aggregate assessments for both mancozeb-derived ETU and ETU from all sources, as appropriate.

(1) Aggregate Risk from Food and Water

ETU Acute Aggregate Risk from Food and Drinking Water. The acute aggregate risk assessment for ETU includes food and drinking water exposure only because there are no other potential pathways of acute exposure. As previously mentioned, EPA took two approaches to calculating acute aggregate risk for ETU. For mancozeb-derived ETU, a DWLOC approach was used. The upper-bound ETU estimated concentration of mancozeb-derived ETU is 25.2 ppb in surface water and 0.21 ppb in ground water, both of which are significantly less than the DWLOC of 123 ppb, and therefore not of concern.

Table 16. Acute Aggregate Risk from Food and Water from Mancozeb-derived ETU

Population Subgroup	Acute DWLOC (ppb)	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)
Females 13-49	123	25.2	0.21

Surface water value derived from modeling and monitoring; ground water value derived from targeted monitoring data.

For ETU from all sources, the Agency incorporated the peak EDWC of 25 ppb into dietary exposure, using DEEM, which was then compared with the aPAD for ETU. At the 99.9th percentile of dietary exposure, acute aggregate exposure from food and water comprises 87% of the aPAD for females age 13-49. Acute risks were calculated for females age 13-49 because the endpoint is based upon developmental effects, which are relevant only to women of child-bearing age. Acute aggregate risk for ETU from all sources is not of concern.

Table 17. Acute Dietary Risk from Food and Water for ETU from All Sources.

Population Subgroup	% a PAD at 99.9th Percentile
Females 13-49 years old	87

ETU Chronic Aggregate Risk from Food and Drinking Water. The chronic aggregate risk assessment for ETU includes only food and drinking water exposures. Potential exposure from residential and recreational uses were not included in the chronic (long term, >6months) aggregate risk assessment because chronic exposure is not expected from these scenarios. The ETU surface water and ground water EDWC values of 0.1 and 0.21 ppb, respectively, were incorporated into a dietary (water only) exposure assessment using the DEEM-FCID™ model and then added to the chronic exposure from food.

Table 18 summarizes chronic aggregate risk from mancozeb-derived ETU and ETU from all sources in food and drinking water. For mancozeb-derived ETU, the aggregate chronic risks are less than 100% cPAD for the general US population and all other population subgroups, and are not of concern. The most highly exposed population subgroup is children 1-2 years old, with aggregate risks of 32% cPAD for surface water and 34% cPAD for groundwater sources of mancozeb-derived ETU. Likewise, for ETU from all sources, aggregate chronic risks are less than 100% cPAD. The most highly exposed subgroup, children 1-2, has aggregate risks of 56 and 58% cPAD. Therefore, the Agency does not have a risk concern for chronic aggregate risk for ETU

from food and drinking water. Exposure from food was approximately an order of magnitude greater than exposure from drinking water.

Table 18. Chronic Aggregate Risk for ETU from Food and Drinking Water

Population Subgroup	Aggregate Risk (%cPAD)			
	Mancozeb-derived ETU		ETU from all Sources	
	Surface Water	Groundwater	Surface Water	Groundwater
General US Population	10	11	17	18
All infants	17	21	33	38
Children 1-2 yr	32	34	56	58

ETU Dietary Cancer Risk from Food and Drinking Water. Dietary cancer risk from food and water was determined for ETU derived from mancozeb and ETU from all sources. Estimated dietary cancer risk from mancozeb-derived ETU in food and water is 1.6×10^{-6} for the general US population, which is within the negligible risk range of 10^{-6} and not of concern. This value is driven by the contribution from food (mango and milk are the major contributors). Estimated dietary cancer risk from ETU from all sources is $\leq 2.1 \times 10^{-6}$ and within the negligible risk range; therefore, EPA does not have a risk concern for dietary cancer risk from food and drinking water. This risk estimate is driven by the contribution of ETU from food; leaf lettuce and apple juice are the major contributors. EPA's dietary cancer risk estimates for ETU for food and water are summarized in Table 19.

Table 19. Summary of ETU Cancer Risk for Food and Water

Population Group	Source of Exposure	Estimated Cancer Risk	
		Mancozeb-derived ETU	ETU from All Sources
General US Population	Food Alone	1.1×10^{-6}	1.9×10^{-6}
	Food and Water	1.6×10^{-6}	2.0×10^{-6} surface water 2.1×10^{-6} groundwater

(2) ETU Short-Term Residential Aggregate Risk

The short-term aggregate risk assessment for ETU includes chronic dietary (food and drinking water) and short-term residential (dermal and inhalation) exposures. The short-term aggregate risks were calculated for adults by aggregating chronic food exposure, chronic drinking water exposure, and golfing or gardening exposures.

Short-Term Residential Handler (food + drinking water + residential). This risk assessment includes dietary exposure from both food and drinking water as well as dermal and inhalation exposure to residential handlers. Mancozeb-derived ETU was the only source of residential exposure considered in this assessment because mancozeb is the only EBDC pesticide registered for use in home gardens. The aggregate short-term MOEs for residential handlers are

significantly higher than the target MOE of 1000. The MOEs range from 62,000 to 190,000, indicating that the short-term risks are not of concern (Table 20).

Table 20. Short-Term Aggregate Handler Risk from ETU, Home Garden

Exposure Scenario	Aggregate Risk, Margin of Exposure (MOE)	
	Mancozeb-derived ETU	ETU from all Sources
Backpack Sprayer	190000	Not Calculated (>62000)
Low-Pressure Handwand	79000	62000

Short-Term Residential Post-Application, Home Garden. Mancozeb-derived ETU was the only source of residential exposure considered in this assessment because mancozeb is the only EBDC pesticide registered for use in home gardens. This risk assessment includes dietary exposure from food and drinking water and dermal exposure from post-application activities in the home garden. Residential post-application exposure and risk have been assessed for both youth and adults. Because post-application exposures are considered short-term in nature, EPA assumes people re-enter the garden on the day of application to harvest vegetables and perform other tasks. Hand harvesting cucurbits was chosen as a surrogate post-application activity that is protective for all other lower exposure activities. Aggregate MOEs for the post-application home garden scenario are significantly higher than the target MOE of 1000, and therefore not of concern to the Agency. ETU short-term aggregate post-application risks for home gardeners are shown in Table 21.

Table 21. Short Term Post-Application Risk from ETU, Home Garden

Population	Short-term Margin of Exposure (MOE)	
	Mancozeb-derived ETU	ETU from All Sources
Youth	26000	Not Calculated (>14550)
Adults	15000	14550

Short-Term Post-Application Recreation, Golfing. This aggregate assessment includes dietary food and water and residential post-application dermal exposure from golfing on treated turf. The Agency assumed people spend up to 4 hours on the golf course and evaluated risks for females age 13-49 because a developmental endpoint was used to assess short-term risks to ETU. The aggregate MOE for golfers is 6400 for mancozeb-derived ETU, and 6200 for ETU from all sources (Table 22). Therefore, EPA does not have a risk concern for this aggregate scenario.

Table 22. Short-Term Aggregate Post-Application Risk, Golfing.

Population Group	Source of Exposure	Short-term Margin of Exposure	
		Mancozeb-derived ETU	ETU from All Sources
Females age 13-49	Food, Water, and Golfing	6400	6200

(3) ETU Aggregate Cancer Risk from Residential Exposure

ETU cancer risks were aggregated using the food and drinking water exposures for the general population and the food, drinking water and recreational exposures for golfers and home gardeners. Aggregate cancer risks for mancozeb-derived ETU are in the range of 1×10^{-6}. Aggregate cancer risk estimates for exposure to ETU from all sources are in the range of 2×10^{-6}; food is the largest contributor. These risk estimates are considered to be within the negligible risk range of 1×10^{-6} and are not of concern. Cancer risks were aggregated using the estimated food, drinking water, and residential exposures for golfers and home gardeners.

Handler, Home Garden (food + water + residential). This aggregate risk assessment includes exposure from diet (food and drinking water) and residential use (combined dermal and inhalation exposure). Mancozeb is the only EBDC pesticide used in home gardens, therefore, only mancozeb-derived ETU is considered in the residential portion of this scenario. For mancozeb-derived ETU, aggregate cancer risk for residential handlers applying mancozeb is 1.3×10^{-6}, which is within the negligible risk range and not of concern. For ETU from all sources, aggregate cancer risk for residential handlers is 2.1×10^{-6}, which is also within the negligible risk range. Dietary exposure from food is the greatest contributor to the aggregate cancer risk.

Post-application, Home Garden (food + water + residential). This assessment includes dietary exposure from food and drinking water and post-application dermal exposure from activities in the home garden. Only mancozeb-derived ETU is considered in the residential portion of this scenario. Hand harvesting curcurbits was chosen as a post-application activity that is a reasonable surrogate for all other lower exposure activities. The ETU aggregate cancer risk estimate for residential post-application exposure in the home garden is 1.5×10^{-6} for mancozeb-derived ETU and 2.3×10^{-6} for ETU from all sources. These estimates fall within the negligible risk range of 10^{-6} and are not of concern.

Post-application, Golfing (food + water + recreational). This assessment includes dietary exposure from food and drinking water and residential post-application dermal exposure from golfing on treated turf. The ETU aggregate post-application cancer risk estimate for adult golfers is 1.3×10^{-6} for mancozeb-derived ETU and 2.1×10^{-6} for ETU from all sources. These values are within the negligible risk range and not of concern.

9. Occupational Risk

Workers can be exposed to mancozeb and mancozeb-derived ETU through mixing, loading, and applying this pesticide to a variety of tree fruits, fruits, vegetables, row crops, sod, turf, ornamentals (including in greenhouses), potatoes and other seed pieces, and during seed treatments. In addition, potential exposure to mancozeb and ETU occurs after application, when workers contact foliage or harvest treated crops or ornamentals during reentry activities. Occupational non-cancer risk to workers is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a NOAEL. However, the occupational assessment does not consider an FQPA SF for sensitive populations (infants or children), nor is it affected by the FQPA database uncertainty factor being applied to dietary exposures for ETU. Thus, the target MOE for occupational risk is 100, and MOEs greater than 100 do not exceed the Agency's level of concern. For occupational cancer risks, as for dietary cancer risk (described in

Section III.A.4.c. of this document), risk estimates within the range of an increased cancer risk of 1 x 10^{-6} (one in a million) are generally not of concern to the Agency. When occupational MOE are less than 100 or occupational cancer risks exceed the range of an increased risk of 1 x 10^{-6}, EPA strives to reduce worker cancer risks through the use of personal protective equipment and engineering controls or other mitigation measures. The Agency generally considers occupational cancer risks within the range of 1 x 10^{-6} to be negligible, but will consider risks as high as 1 x 10^{-4} (1 in 10,000 persons) when all mitigation measures that are practical and feasible have been applied, and when evaluating the advantages conveyed with the use of the pesticide. The cancer risks for mancozeb are as a result of exposure to ETU.

This section of the document on occupational risk refers to mancozeb-derived ETU from three sources, ETU formed in tank mixes, ETU formed in the body by metabolic conversion, and ETU formed as in the environment through degradation. Both handler and post-application assessments considered ETU from metabolic conversion and conversion in tank mixes. Handler assessments addressed combined dermal and inhalation exposures, but post-application risks were derived solely from dermal exposure because of the low vapor pressure of mancozeb.

Occupational risk is assessed based on exposures at the time of application (termed "handler" exposure) and following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the labeled application rate. Post-application risk is assessed for activities such as scouting, irrigating, pruning, and harvesting and is based on dermal exposure estimates. Note that occupational risk estimates are intended to represent pesticide workers, and on this basis assumptions are made concerning acres treated per day and the seasonal duration of exposure.

For more information on the assumptions and calculations of potential risks to workers handling mancozeb or working in mancozeb treated areas, see the document, *"Mancozeb: 2nd Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document,*" dated May 31, 2005, and available in the public docket OPP-2005-0176.

a. Mancozeb and ETU Handler Assessments

Risks for occupational handlers addressed the following scenarios: mixer/loader, applicator, mixer/loader/applicator, and flagger, seed piece treatment and planting, and seed treatment (including a variety of individual and combined tasks). These scenarios were used to estimate exposures based on application of a variety of formulations (wettable powder, dry flowables, liquid flowables, liquid dips and dusts), and using a variety of application methods, such as groundboom, aerial, chemigation, and high- and low-pressure handheld equipment, as well as seed and seed piece treatment equipment.

There were no chemical-specific handler data, so unit exposures from PHED were used to estimate exposures for a variety of clothing scenarios and combinations of personal protective equipment (PPE) and engineering controls. Standard assumptions were used for the number of

acres treated, body weight, hours worked, etc., for most handler scenarios. For the potato seed-piece use, assumptions were based on current product labels. For seed treatment scenarios, unit exposures were derived using the amount of seed treated was estimated based on seed planting rates on a per acre basis, and assuming 80 acres planted per day.

Current mancozeb labels require double layer personal protective equipment (PPE) and a chemical resistant apron for mixing/loading and double layer PPE without the apron for application. Double layer PPE consists of a long-sleeved shirt, long pants, shoes, socks, gloves, and coveralls. Mancozeb labels do not require respiratory protection.

For short- and intermediate-term exposures, mancozeb MOEs are determined by comparing exposure estimates for specific scenarios with the inhalation NOAEL of 21 mg/kg/day from a 90 day rat inhalation study. No dermal endpoint was identified, and no effects were noted in short- or intermediate-term toxicity dermal studies; therefore, dermal exposure was not assessed. EPA considers an inhalation MOE of 100 to be adequately protective for worker exposure.

For chronic exposure to mancozeb, dermal MOEs are determined by comparing exposure estimates with a NOAEL of 4.8 mg/kg/day for a chronic/carcinogenicity study in rats. An absorption factor of 1% was used for chronic dermal exposure because the chronic dermal NOAEL was based upon a oral study. Chronic inhalation MOEs are determined by comparing exposure with a NOAEL of 21 mg/kg/day from a 90 day rat inhalation study.

b. Handler Exposure Scenarios for Mancozeb

The Agency has determined that individuals who mix, load, apply, or otherwise handle mancozeb may be exposed to both mancozeb and ETU. The occupational exposure scenarios evaluated for mancozeb use in agriculture and for seed and seed-piece treatment are listed below.

Agricultural Crops

- Mixing/loading wettable powder (WP), dry flowables (DF), or liquids;
- Applying using aerial, groundboom, airblast, turfgun or high-pressure handwand application methods;
- Mixing/loading/applying WP with a low-pressure handwand, backpack sprayer or turfgun;
- Mixing/loading/applying DF with a low-pressure handwand, backpack sprayer or turfgun;
- Mixing/loading/applying liquids with a low-pressure handwand, backpack sprayer or turfgun; and
- Flagging aerial application

Seed-Piece Treatments

- Mixing/loading WP, DF, liquids or dusts;
- Loading treated seed pieces for tractor planting; and
- Tractor planting treated seed pieces.

Seed Treatments

- Mixing/loading WP, DF, or liquids;
- Loading/applying
- Bagging;
- Sewing bags shut;
- Handler performing multiple activities;
- Planter box seed treatment; and
- Seed planter.

c. Occupational Handler Risk Summary

Short- and Intermediate-Term Risks. Only inhalation MOEs were calculated for short- and intermediate-term mancozeb exposures because no effects were observed in the mancozeb 28 day dermal toxicity study at the limit dose. For some of the mixer/loader scenarios involving the WP formulation, the risks are of concern and respiratory protection is required to achieve risk targets. The risks for mixing and loading DF and liquid flowable formulations are much lower and respiratory protection is not needed. The risks for the remaining scenarios are not of concern. Most of the labels do not require respiratory protection. Short-term handler inhalation risks for mancozeb are summarized in Table 24 below. Please note that risk estimates were not provided for mixer/loader/applicator for backpack sprayer (WP, DF) or high-pressure handwand (DF) due to lack of worker exposure data. However, these risk estimates are not expected to be greater than for handlers mixing, loading, and applying with a low-pressure handwand because the application scenarios are similar.

Table 24. Summary of Short-Term Handler Risks for Mancozeb

Formulation and Application Method	Typical Crop(s)	Application Rate (lbs ai/A)	Area Treated (A/day)	Short-Intermediate Term Inhalation Margin of Exposure (MOE)		
				Baseline (No Respirator)	PF5 Respirator	PF10 Respirator
Mixer/Loaders (M/L)						
Wettable Powder (WP) for Aerial Application or Chemigation	turf (sod farms)	17.4	350	5.6	28	56*
	small grains, cotton cucurbits potatoes, sugar beets sweet corn	1.6 2.4 1.6 1.2	1200 350 350 350	18 41 61 81	89 200 300 410	180 410 610 810
WP for Groundboom	turf (sod farms) turf (golf courses)	17.4 17.4	80 40	25 49	120 250	250 490

Formulation and Application Method	Typical Crop(s)	Application Rate (lbs ai/A)	Area Treated (A/day)	Short-Intermediate Term Inhalation Margin of Exposure (MOE)		
				Baseline (No Respirator)	PF5 Respirator	PF10 Respirator
	Cranberries	4.8	80	89	440	890
	Small grains, cotton	1.6	200	110	530	>1000
	Grapes (East)	3.2	80	130	670	>1000
	Cucurbits	2.4	80	180	890	>1000
	Grapes (West)	2.0	80	210	>1000	>1000
	Potatoes, Sugar beets	1.6	80	270	>1000	>1000
	Ornamentals	1.6	40	530	>1000	>1000
WP for Airblast	Pear psylla	6.4	40 for all crops	130	670	>1000
	Apples	4.8		180	890	>1000
	Grapes (East)	3.2		270	>1000	>1000
	Grapes (West); Papaya	2		430	>1000	>1000
WP for Turfgun	Turf	17.4	5	390	>1000	>1000
WP for High Pressure Handwand	Pachysandra, Conifers, Ornamentals	14	10	240	930	>1000
DF Aerial or Chemigation	Turf (sod farms)	17.4	350 to 1200			
	All other crops	1.2-14	350 to 1200	≥310	Not assessed	
DF Groundboom, Airblast, Turfgun or HP Handwand	Turf (sod farms)	17.4	5 to 200	≥1400	Not assessed	
	All other crops	1.2-14	5 to 200	≥880	Not assessed	
Liquids for Aerial Application or Chemigation	turf (sod farms)	17.4	350 to 1200	≥ 200	Not assessed	
	all other crops	1.2-14				
	all other crops	1.2- 14	350 to 1200	≥ 200	Not assessed	
Liquids for Groundboom, Airblast, Turfgun or HP Handwand	turf (sod farms)	17.4	5 to 200	≥ 880	Not assessed	
	all other crops	1.2-14	5 to 200	≥ 880	Not assessed	
Applicators						
Aerial Application	Turf (sod farms)	1.2 - 17.4	350 to 1200	≥3500	Not assessed	
Groundboom Application	Other Crops	1.2 - 17.4	40 to 200	≥1400	Not assessed	
Airblast Application	Other Crops	2.0 - 6.4	40	≥ 1300	Not assessed	
Turfgun Application	Turf (sod farms)	17.4	5	>1000	>1000	>1000

Formulation and Application Method	Typical Crop(s)	Application Rate (lbs ai/A)	Area Treated (A/day)	Short-Intermediate Term Inhalation Margin of Exposure (MOE)		
				Baseline (No Respirator)	PF5 Respirator	PF10 Respirator
HP Handwand Application	Ornamentals	1.2 to 14	10	>1000	>1000	>1000
Mixer/Loader/Applicators (M/L/A)						
M/L/A WP LP Handwand	Pachysandra conifers ornamentals	14 3.2 1.6	0.4	240 >1000 >1000	>1000 >1000 >1000	>1000 >1000 >1000
M/L/A WP Turfgun	Turf	17.4	5	270	>1000	>1000
M/L/A DF Turfgun	Turf	17.4	5	>1000	>1000	>1000
M/L/A Liquids LP Handwand	Ornamentals	1.2 - 14	0.4	≥8700	Not assessed	
M/L/A Liquids Backpack Sprayer	Ornamentals	1.2 - 14	0.4	≥8700	Not assessed	
M/L/A Liquids Turfgun	Turf	17.4	5	>1000	>1000	>1000
MOEs for Flagger						
Aerial Spray Applications	All crops above	1.2 - 17.4	350	≥690	Not assessed	

Respirator Types: PF5 denotes Filtering Face piece Respirator, PF10 denotes Half Face Cartridge Respirator.
* MOE for turf is calculated to be > 1000 with engineering controls (water soluble packaging).

As shown in table 24 above, short- and intermediate-term inhalation MOEs were > 100, and therefore not of concern, for all but two scenarios. The Agency has risk concerns for workers mixing/loading the WP for aerial application or chemigation use on turf with a PF 5 dust-mist respirator (MOE is 28 for sod farms) and small grains (MOE is 89). The MOE for application to turf on sod farms is > 100 only when engineering controls (water soluble packets) are used.

The Agency also assessed the risk of ETU from spray mix and ETU metabolized from absorbed mancozeb. EPA calculated short- and intermediate-term MOEs from inhalation and dermal exposure combined for the same scenarios listed in Table 24. At baseline, short- and intermediate-term ETU MOEs range from 7 to 670. MOEs are of concern for some high volume mixing/loading WP scenarios and require respiratory protection or engineering controls to achieve the target MOE. The engineering controls are necessary only for turf. Because short- and intermediate-term risk from ETU are the same as or lower than for mancozeb, the ETU risks are not presented in detail in this document but may be found in the May 31, 2005 revised occupational and residential exposure assessment for mancozeb.

Chronic Exposure to Mancozeb. The Agency evaluated chronic handler risks only for the greenhouse and nursery uses of mancozeb. No other mancozeb uses result in chronic exposures (>180 contiguous days/year). Chronic worker risks, expressed as MOEs, are of concern at baseline PPE (single layer, no gloves) for two scenarios, mixing/loading wettable powder for high-pressure handwand and mixing/loading liquids for low-pressure handwand. However, MOEs are all above 100, and not of concern, when single layer PPE (i.e., gloves) are worn. Estimated chronic handler risks for mancozeb are summarized in Table 25 below. Please note that the Agency did not assess risks for mixer/loader/applicator for low-pressure handwand or backpack sprayer using dry flowable or for low-pressure handwand using liquids. Because EPA did not have sufficient data to assess these scenarios, a worker exposure monitoring study is required in the DCI for this RED.

Table 25. Summary of Mancozeb Chronic MOEs for Crop Treatment

Exposure Scenario	Crop Type	Application Rate (lb ai/acre)	A/day	Margin of Exposure (MOE)	
				Baseline	Single Layer No Respirator
Mixer/Loader					
Mix/Load WP for High-Pressure Handwand	pachysandra ornamentals	14 1.2	10	**52** 600	210 >1000
Mix/Load DF for High-Pressure Handwand	pachysandra ornamentals	14 1.2	10	>1000 >1000	>1000 >1000
Mix/Load Liquids for High-pressure Handwand	pachysandra ornamentals	14 1.2	10	Not Done Not Done	>1000 >1000
Applicator					
High-Pressure Handwand Application	pachysandra ornamentals	14 1.2	10	170 >1000	500 >1000
Mixer/Loader/Applicator (M/L/A)					
M/L/A WP with Low- Pressure Handwand	pachysandra ornamentals	14 1.2	0.4 0.4	Not Done Not Done	180 >1000
M//L/A Liquids with Low-pressure Handwand	pachysandra ornamentals	14 1.2	0.4	60 700	>1000
M/L/A Liquids with Backpack	pachysandra ornamentals	14 1.2	0.4	Not Done Not Done	>1000 >1000

Baseline = Single Layer Clothing without gloves

EPA also evaluated chronic risks for ETU for greenhouse and nursery uses. Risks are of concern for a few scenarios such as mixing/loading/applying wettable powders to pachysandra; however, the registrants have requested cancellation of this use. Estimated chronic risks from ETU are summarized in Table 26 below.

Table 26. Summary of ETU Chronic MOEs for Crop Treatment

Exposure Scenario	Crop Type	Application Rate, lb ai/A	Area Treated, A/day	Margin of Exposure (MOE)		
				Baseline	Single Layer No Respirator	Single Layer, PF 5 Respirator
Mix/Load WP for HP Handwand	pachysandra ornamentals	14 1.2	10	13 150	26 310	110 1,300
Mix/Load DF for HP Handwand	pachysandra ornamentals	14 1.2	10	720 >1000	720 8400	1,200 13,000
Mix/Load Liquids for HP Handwand	pachysandra ornamentals	14 1.2	10	30 350	790 9200	2,200 25,000
HP Handwand Application	pachysandra ornamentals	14 1.2	10	46 540	110 1300	160 1,900
Mix/Load/Apply WP with LP Handwand	pachysandra ornamentals	14 1.2	0.4	No Data	25 290	81 940
Mix/Load/Apply Liquids with LP Handwand	pachysandra ornamentals	14 1.2	0.4	17 200	790 9600	2,200 29,000
Mix/Load/Apply Liquids with Backpack Sprayer	pachysandra ornamentals	14 1.2	0.4	No Data	470 5,400	750 8,800

Cancer Risks from Lifetime Exposure. The cancer risks for application of mancozeb to agricultural crops result from exposure to ETU. Cancer risk estimates assume that a handler is exposed 30 days per year for a 35 year work life over a 70 year lifetime. To calculate cancer risks, the Agency amortized daily exposure over a lifetime and then multiplied the resulting lifetime average daily dose by the cancer potency factor, or Q_1*, for ETU. Cancer risk was based on combined dermal and inhalation exposures to ETU.

For most handler exposure scenarios, cancer risk estimates were below 1 x 10^{-4} without mitigation. Most cancer risks for application of mancozeb to agricultural crops are below 1 x 10^{-4} with single layer PPE (which includes gloves but not respirators), and all of the cancer risks are below 1 x 10^{-4} with additional PPE (respirators) or engineering control. In general, risks for mixing/ loading dry flowables or liquids are much lower than for wettable powders. Many of the scenarios that involve the mixing/loading of wettable powder have risks of concern with the PPE required on current labels and require respirators to achieve Agency risk targets. In a few cases, such as those scenarios involving high application rates and large acreage treated, engineering controls such as water soluble bags are needed to address risk concerns. These estimated risks are generally lower if the dry flowable or liquid formulations are used.

Table 27. Summary of Cancer Risks from Mancozeb-derived ETU.

Formulation and Application Method	Typical Crop(s)	Application Rate* (lbs ai/A)	Area Treated (A/day)	Cancer Risk Estimate (ETU derived from mancozeb)			
				Single Layer	Single Layer + PF 5 Respirator	Double Layer + PF 5 Respirator	Engineering Controls**
Mixer/Loaders (M/L)							
Wettable Powder (WP) for Aerial Application or Chemigation	(A) turf: sod farms	17.4	350	7.4 x 10-4	1.8 x 10-4	1.7 x 10-4	6 x 10-6
	(B) small grains, cotton	1.6	1200	2.3 x 10-4	5.6 x 10-5	5.3 x 10-5	1.9 x 10-6
	cucurbits	2.4	350	1.0 x 10-4	2.4 x 10-5	2.3 x 10-5	8.3 x 10-7
	potatoes, sugar beets	1.6	350	6.8 x 10-5	1.6 x 10-5	1.6 x 10-5	5.6 x 10-7
	sweet corn	1.2	350	5.1 x 10-5	1.2 x 10-5	1.2 x 10-5	4.2 x 10-7
WP for Groundboom	(C) turf: sod farms	17.4	80	1.7 x 10-4	4.1 x 10-5	4 x 10-5	1.4 x 10-6
	turf: golf courses	17.4	40	8.4 x 10-5	2 x 10-5	2 x 10-5	7 x 10-7
	(D) cranberries	4.8	80	3 x 10-5	7 x 10-6	6.6x 10-6	2.4 x 10-7
	small grains, cotton	1.6	200	4 x 10-5	9.3 x 10-6	9 x 10-6	3.2 x 10-7
	grapes (East)	3.2	80	2.1 x 10-5	5.1 x 10-6	5 x 10-6	1.7 x 10-7
	cucurbits	2.4	80	2.3 x 10-5	5.6 x 10-6	5.3 x 10-6	2 x10-7
	grapes (West)	2.0	80	1.5 x 10-5	3.5 x 10-6	3.3 x 10-6	1.2 x 10-7
	potatoes, sugar beets	1.6	80	1.6 x 10-5	3.7 x 10-6	3.5 x 10-6	1.3 x 10-7
	ornamentals	1.2	40	5.8 x 10-6	1.4 x 10-6	1.3 x 10-6	4.8 x 10-8
WP Airblast	(E) pome fruits (West)	3.1		1.5 x 10-5	3.6 x 10-6	3.4 x 10-6	1.2 x 10-7
	pome fruits (East)	2.1	40	1 x 10-5	2.4 x 10-6	2.3 x 10-6	8.3 x 10-8
	grapes (East)	2.2	for all crops	1.1 x 10-5	2.6 x 10-6	2.4 x 10-6	8.7 x 10-8
	grapes (West)	1.5		7.3 x 10-6	1.7 x 10-6	1.7 x 10-6	6.8 x 10-8
WP for Turfgun	(F) turf	17.4	5	1.1 x 10-5	2.5 x 10-6	2.4 x 10-6	8.6 x 10-8

Formulation and Application Method	Typical Crop(s)	Application Rate* (lbs ai/A)	Area Treated (A/day)	Cancer Risk Estimate (ETU derived from mancozeb)			
				Single Layer	Single Layer + PF 5 Respirator	Double Layer + PF 5 Respirator	Engineering Controls**
WP High Pressure Handwand	(G) pachysandra conifers ornamentals	14 3.2 1.2	10	1.7 x 10-5 3.9 x 10-6 1.5 x 10-6	4.1 x 10-6 9.3 x 10-7 3.5 x 10-7	3.9 X 10-6 8.9 x 10-7 3.3 x 10-7	1.4 x 10-7 3.2 x 10-8 1.2 x 10-8
DF Aerial or Chemigation	(H) Turf (sod farms)	17.4	350	2.7 x 10-5	1.7 x 10-5	1.3 x 10-5	Not Applicable
	(I) All other crops	1.2-14	350 to 1200	1.9 x 10-6 to 8.5 x 10-6	1.2 x 10-6 to 5.3 x 10-6	8.7 x 10-7 to 4 x 10-6	Not Applicable
DF Groundboom, Airblast, Turfgun or HP Handwand	(J) turf (sod farms)	17.4	80	6.1 x 10-6	3.8 x 10-6	2.9 x 10-6	Not Applicable
	(K) all other crops	1.2-14	10 to 200	2.1 x 10-7 to 1.4 x 10-6	1.3 to 8.8 x 10-7	1 to 6.6 x 10-7	Not Applicable
Liquids for Aerial Application or Chemigation	(L) turf (sod farms)	17.4	350	2.5 x 10-5	8.9 x 10-6	7.6 x 10-6	3.2 x 10-6
	(M) all other crops	1.2-14	350 to 1200	1.7 to 7.8 x 10-6	2.8 x 10-6 to 6.1 x 10-7	2.4 x 10-6 to 5.2 x 10-7	1 x 10-6 to 4.4 x 10-7
Liquids for Groundboom, Airblast, Turfgun or HP Handwand	(N) turf (sod farms)	17.4	80	5.6 x 10-6	2 x 10-6	1.7 x 10-6	7.4 x 10-7
	(O) all other crops	1.2-14	5 to 200	1.3 x 10-6 to 4.6 x 10-8	1.5 x 10-7 to 1.4 x 10-8	4.7 x 10-7 to 1.8 x 10-8	1.7 x 10-7 to 2.5 x 10-8

Formulation and Application Method	Typical Crop(s)	Application Rate* (lbs ai/A)	Area Treated (A/day)	Cancer Risk Estimate (ETU derived from mancozeb)			
				Single Layer	Single Layer + PF 5 Respirator	Double Layer + PF 5 Respirator	Engineering Controls**
Applicators (Risk Values are Independent of Formulation)							
(P) Aerial Application	Turf (sod farms)	17.4	350	Not Assessed	Not Assessed	Not Assessed	2.5 x 10-6
(Q) Groundboom Application	Turf (sod farms)	17.4	80	3.7 x 10-6	1.4 x 10-6	1.3 x 10-6	4.7 x 10-7
	Other Crops	1.2 - 17.4	40 to 200	1.7 to 8.4 x 10-7			
Airblast Application	Other Crops	2.0 - 6.4	40	1.4 to 2.8 x 10-6	1.6 x 10-6 to 7.9 x 10-7	1.6 x 10-6	1 x 10-7 to 2.2 x 10-8
Turfgun Application	Turf (sod farms)	17.4	5	3.1 x 10-6	2.9 x 10-6	2.1 x 10-6 to 4.8 x 10-7	No Data
HP Handwand Application	Ornamentals	1.2 to 14	10	3.9 x 10-6 to 9 x 10-7	2.7 x 10-6 to 2.4 x 10-7	2.1 x 10-6 to 4.8 x 10-7	No Data
Mixer/Loader/Applicators (M/L/A)							
M/L/A WP with Low Pressure Handwand	pachysandra conifers ornamentals	14 3.2 1.6	0.4	1.9 x 10-5 4.3 x 10-6 1.6 x 10-6	5.5 x 10-6 1.3 x 10-6 4.7 x 10-7	For pachysandra, 5 x 10-6 For other crops, ≤1 x 10-6	No Data
M/L/A WP with Turfgun	Turf	17.4	5	1.8 x 10-5	5.8 x 10-6	4.5 x 10-6	No Data
M/L/A DF with Turfgun	Turf	17.4	5	2.8 x 10-6	2.4 x 10-6	1.4 x 10-6	No Data
M/L/A Liquids with LP Handwand	ornamentals	1.2 - 14	0.4	5.6 x 10-7	2.0 x 10-7	1.8 x 10-7	No Data

Formulation and Application Method	Typical Crop(s)	Application Rate* (lbs ai/A)	Area Treated (A/day)	Cancer Risk Estimate (ETU derived from mancozeb)			
				Single Layer	Single Layer + PF 5 Respirator	Double Layer + PF 5 Respirator	Engineering Controls**
M/L/A Liquids with Backpack Sprayer	ornamentals	1.2 - 14	0.4	1.1 x 10-6 to 9.3 x 10-8	7.2 x 10-7 to 6.2 x 10-8	4.9 x 10-7 to 4.2 x 10-8	No Data
M/L/A Liquids with Turfgun	Turf	17.4	5	2.4 x 10-6	2 x 10-6	1.1 x 10-6	No Data
Flagger							
Flag Aerial Spray Applications	all crops above	1.2 - 17.4	350	2.1 to 9.1 x 10-6	1 x 10-6 to 4.4 x 10-6	4.2 x 10-6 to 9.8 x 10-7	4.2 x 10-8 to 1.8 x 10-7

Respirator Types: PF5 = Filtering Face piece Respirator, PF10 = Half Face Cartridge Respirator
* Average rate (from NASS data) used to calculate cancer risk. **Engineering controls are water soluble package for WP formulation, closed mixing/loading for other formulations, and closed cabs for applicators.

Seed and Seed-Piece Treatment. The noncancer risk estimates for mancozeb seed treatment are of concern only when mixing or loading the wettable powder formulations and require respiratory protection or engineering controls to achieve the target MOE. The risks for loading the dry flowable or liquid flowable formulations are not of concern and do not require respiratory protection. The risks of applying the seed treatment and handling the treated seed are not of concern. At baseline, cancer risks for seed treatment are in the 10^{-4} to 10^{-5} range for mixers and loaders and in the 10^{-6} to 10^{-7} range for workers involved in noncontact activities, such as packaging treated seed. With a PF 5 respirator, risks for mixing/loading WP formulations range from 2.9×10^{-5} to 1.8×10^{-4}. With engineering controls, risks for mixers/loaders range from 2.4×10^{-7} to 1.5×10^{-6}.

Noncancer risk estimates for loading dusts for seed piece treatment are also of concern and require respiratory protection (PF 5 respirator). With a single layer of protective clothing, cancer risks for workers loading dusts are 1.2×10^{-4} for commercial seed piece treatment and 3.3×10^{-6} for on-farm seed piece treatment. With a PF 5 respirator, risks are 2.7×10^{-5} for commercial and 8.1×10^{-7} for on-farm treatment. With engineering controls, risks are 8.8×10^{-7} for commercial and 2.9×10^{-8} for on farm. The risks of applying the dusts to seed pieces could not be evaluated because there is no exposure data for this scenario; however, the Agency believes that this risk will not be greater than risks to loaders.

Noncancer risk estimates for seed and seed-piece treatment are summarized in Table 28. ETU cancer risks for application of mancozeb to seeds and seed pieces were calculated using 30 exposure days per year for commercial treatment and 10 days per year for on-farm treatment. Estimated cancer risks for seed and seed-piece treatment are summarized in Table 29. Risk estimates were not provided for the following scenarios due to lack of worker exposure data: applicator using liquid dip for seed-piece treatment, applicator using dusts for commercial or on-farm seed treatment, and secondary handling for hand planting treated seed pieces. These data will be required in the DCI for this RED.

Table 28. Noncancer Risk Estimates for Mancozeb for Seed and Seed-Piece Treatment

Exposure Scenario	Seed or Seed Piece Crop	Application Rate (lb ai/cwt unless otherwise stated)	Short- and Intermediate-Term Inhalation MOEs	
			Baseline	PF5
Seed-Piece Treatment				
Mixer and/or Loader				
Load Dusts for Commercial Seed Piece Treatment	potatoes	0.098	35	170
Load Dusts for On-Farm Seed Piece Treatment			440	2200
Secondary Handler				
Load Treated Seed Pieces for Tractor Planting	potatoes	1.96 lb ai/acre	11000	Not assessed
Tractor Plant Treated Seed Pieces			16000	Not assessed
Commercial Seed Treatment				
Mix/Load WP	cotton	0.0015	140	710
	tomato	0.0040	97	490
	flax	0.0036	59	300
	safflower	0.0010	48	240
	peanuts	0.0080	36	180
	wheat	0.0017	29	140
	rye	0.0018	26	130
	rice	0.0020	24	120
	field corn	0.0027	23	110
	barley	0.0021	23	110
	sorghum	0.0023	21	100
	oats	0.0032	15	74
Mix/Load Dry Flowable	Same as above		≥ 850	Not assessed
Mix/Load Liquids	Same as above		≥ 540	
Loader/Applicator	Same as above		≥ 1900	Not assessed
Bagger	Same as above		≥ 4100	Not assessed
Sewer	Same as above		≥ 2800	
Multiple Activities	Same as above		≥ 410	Not assessed

Exposure Scenario	Seed or Seed Piece Crop	Application Rate (lb ai/cwt unless otherwise stated)	Short- and Intermediate-Term Inhalation MOEs	
			Baseline	PF5
On-Farm Seed Treatment and Planting				
Planter Box Seed Treatment Using Dusts	sorghum safflower corn rye barley wheat oats rice	0.0017 0.0025 0.0017 0.0011 0.0013 0.0010 0.0020 0.0028	≥ 36000	Not assessed
Planter Box Seed Treatment Using Slurries	tomato safflower sorghum cotton corn flax rye barley wheat oats rice peanuts	0.0042 0.0011 0.0023 0.0016 0.0027 0.0035 0.0018 0.0021 0.0016 0.0031 0.0021 0.008	≥ 14000	Not assessed
Seed Planter	Same as above		≥ 4800	Not assessed

PPE Codes: Baseline = Single Layer Clothing without gloves PF5 = Filtering Face piece Respirator,

Table 29. Summary of ETU Cancer Risks for Seed and Seed-Piece Treatment Use

Exposure Scenario	Seed or Seed-Piece Crop	Application Rate (lb ai/cwt unless otherwise stated)	Cancer Risk Estimate for this Level of PPE			
			Baseline	Single Layer	Single Layer + PF 5 respirator	Engineering Controls*
Mixer and/or Loader						
Load Dusts for Commercial Seed-Piece Treatment	potatoes	0.098	2.1 x 10-4	1.2 x 10-4	2.7 x 10-5	8.8 x10-7
Load Dusts for On-Farm Seed-Piece Treatment			7.4 x 10-6	3.3 x 10-6	8.1 x 10-7	2.9 x10-8
Secondary Handler						
Load Treated Seed Pieces for Tractor Planting	potatoes	1.96 lb ai/acre	1.4 x 10-7	1.4 x 10-7	3.9 x 10-8	No Data
Tractor Plant Treated Seed Pieces			1.1 x 10-7	1.1 x 10-7	3.2 x 10-8	2.0 x 10-8
Commercial Seed Treatment						
Mix/Load WP (Although WP is seldom used in seed treatment, scenario is included because use is on labels)	cotton tomato flax safflower peanuts wheat rye rice field corn	0.0015 0.0040 0.0036 0.0010 0.0080 0.0017 0.0018 0.0020 0.0027	5.9 x 10-5 8.7 x 10-5 1.4 x 10-4 1.8 x 10-4 2.4 x 10-4 2.9x 10-4 3.2 x 10-4 3.5 x 10-4 3.7 x 10-4	2.9 x 10-5 4.3 x 10-5 7 x 10-5 8.7 x 10-5 1.2 x 10-4 1.4 x 10-4 1.6 x 10-4 1.7 x 10-4 1.8 x 10-4	7 x 10-6 1 x 10-5 1.7 x 10-5 2.1 x 10-5 2.8 x 10-5 3.4 x 10-5 3.8 x 10-5 4.2 x 10-5 4.3 x 10-5	2.4 x 10-7 3.5 x 10-7 5.7 x 10-7 7.1 x 10-7 9.5 x 10-7 1.2 x 10-6 1.3 x 10-6 1.4 x 10-6 1.5 x 10-6
Mix/Load Liquids	Same as above		1.6 x 10-4 to 8.4 x 10-5	6 x 10-6 to 9.7 x 10-7	2.2 x 10-6 to 8.3 x 10-7	1.3 to 7.8 x 10-7
Loader/Applicator	Same as above		No Data	2.5 x 10-6 to 4.1 x 10-7	1.5 x 10-6 to 2.4 x 10-7	No Data
Bagger	Same as above		1.2 x 10-6 to 1.8 x 10-7	No Data	No Data	No Data

Exposure Scenario	Seed or Seed-Piece Crop	Application Rate (lb ai/cwt unless otherwise stated)	Cancer Risk Estimate for this Level of PPE			
			Baseline	Single Layer	Single Layer + PF 5 respirator	Engineering Controls*
Sewer	Same as above		1.7 x 10-6 to 2 x 10-7	No Data	No Data	No Data
Multiple Activities	Same as above		No Data	1.4 to 8.6 x 10-6	3.5 x 10-6 to 5.7 x 10-7	No Data
On-Farm Seed Treatment and Planting						
Planter Box Seed Treatment Using Dusts	sorghum safflower corn rye barley wheat oats rice	0.0017 0.0025 0.0017 0.0011 0.0013 0.0010 0.0020 0.0028	No Data	6.3 x 10-7 8.4 x 10-7 4.6 x 10-7 2.1 x 10-6 2.3 x 10-6 3 x 10-6 2.3 x 10-6 3.8 x 10-6	6.3 x 10-7 8.4 x 10-7 4.5 x 10-7 2.1 x 10-6 2.3 x 10-6 3 x 10-6 2.3 x 10-6 3.8 x 10-6	No Data
Planter Box Seed Treatment Using Slurries	tomato safflower sorghum cotton corn flax rye barley wheat oats rice peanuts	0.0042 0.0011 0.0023 0.0016 0.0027 0.0035 0.0018 0.0021 0.0016 0.0031 0.0021 0.008	No Data	2.5 x 10-8 5.1 x 10-7 3.8 x 10-7 3.8 x 10-7 4.6 x 10-7 1.1 x 10-6 2.1 x 10-6 2.3 x 10-6 3 x 10-6 2.3 x 10-6 3.8 x10-6 3.5 x 10-6	2.5 x 10-8 5.0 x 10-7 3.8 x 10-7 3.8 x 10-7 4.5 x 10-7 1.1 x 10-6 2.1 x 10-6 2.3 x 10-6 3 x 10-6 2.3 x 10-6 3.8 x10-6 3.5 x 10-6	No Data
Seed Planter	Same as above		No Data	2 x 10-9 to 5.4 x 10-7	1.2 x 10-9 to 3.2 x 10-7	No Data

* Engineering control is closed capture system for wettable powders and dusts.

d. Occupational Post-Application Risk

The post-application occupational risk assessment considers exposure to chemical mancozeb and mancozeb-derived ETU from entering treated fields, orchards, and greenhouses. Given the nature of activities in these locations and that mancozeb is applied at various times during plant growth, contact with treated surfaces is likely. A variety of post-application exposure scenarios were identified by the type of activity involved and by the range of exposure expected, i.e., low, medium and high exposure activities. Examples of low exposure activities include irrigation and scouting; medium exposure activities may involve scouting of mature plants, or, in greenhouses, hand pinching chrysanthemum plants. Potential high exposure activities include hand harvesting cut flowers and thinning and pruning apples. Only dermal exposures were evaluated in the post-application worker assessment. EPA believes the post-application inhalation exposure will be minimal because of the high dilution one would expect outdoors and the relatively low vapor pressure of 9.8×10^{-8} mmHg at 25°C .

EPA used dislodgeable foliar residue (DFR) and turf transferable residue (TTR) data in the post-application risk assessment. The Agency's standard transfer coefficients were also used to assess worker reentry exposures. EPA has received post-application DFR data on mancozeb and ETU for grapes, greenhouse and field tomatoes, and apples, as well as TTR data from treated turf. DFR data do not cover all crops treated with mancozeb; therefore, the existing DFR data were extrapolated to the remaining crops by considering the effects of application method, crop type, and climate.

Post-application exposures are calculated by considering transferable residue levels in areas where people work and the kinds of jobs or tasks that are required to produce agricultural commodities and to maintain other areas such as golf courses. These factors are represented by DFR or TTR concentrations and by transfer coefficients. Exposures are calculated by multiplying these factors by an 8 hour work day. Exposures are then normalized by body weight and adjusted for dermal absorption (if necessary) to calculate absorbed doses. MOEs were then calculated. Post-application risks diminish over time because mancozeb residues eventually dissipate in the environment. As a result, risk values were calculated over time based on changing residue levels.

The post-application risk estimates are considered when setting a restricted entry interval for a pesticide. The Worker Protection Standard (WPS) for Agricultural Pesticides defines a Restricted-Entry Interval (REI) as the duration of time that must elapse before residues decline to a level at which entry into a previously treated area and engaging in any task or activity would not result in exposures of concern. The WPS currently prohibits entry by workers until at least 24 hours following application and until any ventilation or inhalation requirements have been met.

At the current REI of 24 hours, there are no non-cancer risks of concern for short- and intermediate-term post-application exposures to mancozeb parent or ETU. For the worst case scenario, re-entry workers performing high contact activities, ETU MOEs range from 180 to 21,000 and are not of risk concern. Therefore, these risk estimates are not being presented here in detail but may be found in the occupational and residential risk assessment. The Agency is

presenting only chronic MOEs for ETU in this document because chronic MOEs for the parent mancozeb are all greater than the chronic MOEs for ETU and not of concern to the Agency. Chronic MOEs for re-entry workers exposed to mancozeb-derived ETU are presented in Table 30 below.

Table 30. ETU Post-Application Chronic Non-Cancer Risks

Crop Group	Chronic MOE on Day of Application (Day 0)				
	Application Rate (lb a.i./acre)	Low Exposure Scenarios	Medium Exposure Scenarios	High Exposure Scenarios	Very High Exposure Scenarios
Cut Flowers	1.2	N/A	N/A	170	N/A
Greenhouse Ornamental Plants	1.2	4300	2700	1200	N/A
Greenhouse Tomatoes	2.4	470	340	240	N/A

N/A, Not applicable.

Available DFR data for mancozeb show that residues on foliage degrade slowly. As a result, predicted cancer estimates also decrease slowly over time. Cancer risk estimates for re-entry workers range from 4×10^{-7} to 4×10^{-5} on the day of mancozeb application for high contact activities. For medium contact activities, estimated cancer risks for re-entry workers range from 2×10^{-7} to 9×10^{-6} on the day of application. For low contact activities, estimated cancer risks range from 7×10^{-8} to 8×10^{-6} on the day of application. EPA considers occupational cancer risks within the range of 10^{-6} to be negligible, but will consider risks as high as 1×10^{-4} (1 in 10,000 persons) when all practical and feasible mitigation measures have been considered. Post-application cancer risks for mancozeb-derived ETU are summarized in Table 31.

Table 31. Post-Application Cancer Risks from ETU (30 days per year)

Crop Group	Cancer Risk on Day of Application (Day 0)				
	Application Rate (lb a.i./acre)	Low Exposure Scenarios	Medium Exposure Scenarios	High Exposure Scenarios	Very High Exposure Scenarios
Berry, low (Cranberry)	3.0	5×10^{-6}	N/A	N/A	N/A
Bunch, bundle (Banana)	2.4	3×10^{-7}	4×10^{-6}	6×10^{-6}	N/A
Bunch, bundle (Tobacco Seedlings)	2.0	2×10^{-7}	N/A	N/A	N/A
Bunch, bundle (Tobacco Fields)	1.5	N/A	N/A	4×10^{-6}	N/A
Cut Flowers	1.2	2×10^{-6}	4×10^{-6}	2×10^{-6}	N/A
Low/medium row crops, West Low/medium row crops, East	1.6 1.6	2×10^{-7} 2×10^{-7}	3×10^{-6} 3×10^{-6}	5×10^{-6} 5×10^{-6}	N/A N/A
Tall row crops , West Tall row crops, East	1.2 1.2	N/A N/A	6×10^{-7} 5×10^{-7}	2×10^{-6} 1×10^{-6}	3×10^{-5} 2×10^{-5}
Ornamental Plants Grown in Greenhouse	1.2	1×10^{-7}	2×10^{-7}	4×10^{-7}	N/A
Papaya	2.0	2×10^{-6}	7×10^{-6}	N/A	N/A

Crop Group	Cancer Risk on Day of Application (Day 0)				
	Application Rate (lb a.i./acre)	Low Exposure Scenarios	Medium Exposure Scenarios	High Exposure Scenarios	Very High Exposure Scenarios
Trees, fruit, deciduous - West Trees, fruit, deciduous - East	3.1 2.1	4×10^{-6} 8×10^{-6}	N/A N/A	1×10^{-5} 3×10^{-5}	N/A N/A
Trees, Christmas - West Trees, Christmas - East	3.2 3.2	5×10^{-6} 1×10^{-5}	1×10^{-5} 4×10^{-5}	N/A N/A	N/A N/A
Turf - California Turf - North Carolina Turf - Pennsylvania	17.4 17.4 17.4	1×10^{-6} 1×10^{-7} 7×10^{-8}	N/A N/A N/A	4×10^{-5} 4×10^{-6} 2×10^{-6}	N/A N/A N/A
Vegetable, cucurbit - West Vegetable, cucurbit - East	2.4 2.4	2×10^{-6} 1×10^{-6}	5×10^{-6} 4×10^{-6}	8×10^{-6} 7×10^{-6}	N/A
Vegetable, fruiting - West Vegetable, fruiting - East	1.4 1.4	9×10^{-7} 9×10^{-7}	1×10^{-6} 1×10^{-6}	2×10^{-6} 2×10^{-6}	N/A N/A
Vegetable, root - West Vegetable, root - East	2.4 2.4	1×10^{-6} 8×10^{-7}	5×10^{-6} 4×10^{-6}	8×10^{-6} 7×10^{-6}	N/A N/A
Vegetable, Stem/Stalk. - West Vegetable, Stem/Stalk - East	1.6 1.6	7×10^{-7} 5×10^{-7}	1×10^{-6} 9×10^{-7}	N/A N/A	N/A N/A
Vine/trellis (grapes) - West Vine/trellis (grapes) - East	1.5 2.2	2×10^{-6} 4×10^{-6}	4×10^{-6} 9×10^{-6}	2×10^{-5} 4×10^{-5}	N/A N/A
EPA assumed 30 days per year of exposure for re-entry workers. N/A, Not applicable.					

e. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers, the Agency's Office of Pesticide Program's Incident Data System, and the California Pesticide Illness Surveillance Program. A total of 11 incidents were reported in the OPP Incident Data System from 1992 to 2001. Most of these incidents involved skin rashes or contact dermatitis while a few involved dizziness and nausea. There were 44 cases reported in the California Pesticide Illness Surveillance Program (1982-1999) in which mancozeb was used alone or was judged to be responsible for the health effects. Most of these cases (33) involved post-application exposure to field residues and the most common effect was skin rashes. Reports in the literature also indicated that mancozeb causes skin sensitization.

The incident report concludes that mancozeb is a documented cause of skin rash and allergic sensitization. This conclusion is supported by the literature and reports from California and the Incident Data System. The prevalence of this problem among workers cannot be determined from available information. Some of the data suggest that the hazards of skin sensitization due to mancozeb residues can persist in the fields for months, long after the original application.

10. Cumulative Assessment

As previously mentioned, the risk estimates summarized in this document are those that result only from the use of mancozeb and ETU derived from mancozeb and the other EBDC chemicals, which are all dithiocarbamates. For the purposes of this reregistration eligibility decision, EPA has concluded that mancozeb does not share a common mechanism of toxicity with other substances. The Agency reached this conclusion after a thorough internal review and external peer review of the data on a potential common mechanism of toxicity.

EPA concluded that the available evidence does not support grouping the dithiocarbamates based on a common toxic effect (neuropathology) occurring by a common mechanism of toxicity (metabolism to carbon disulfide). After a thorough internal and external peer review of the existing data bearing on a common mechanism of toxicity, EPA concluded that the available evidence shows that neuropathology can not be linked with carbon disulfide formation. For more information, please see the December 19, 2001 memo, *"The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity*"on the internet at http://www.epa.gov/oppsrrd1/cumulative/dithiocarb.pdf.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment for mancozeb is presented below. More detailed information associated with the environmental risk from the use of mancozeb can be found in the following document, *"Environmental Fate and Ecological Risk Assessment for Mancozeb, Section 4 Reregistration for Control of Fungal Diseases on Numerous Crops, a Forestry Use on Douglas Firs, Ornamental Plantings, and Turf (Phase 3 Response),"* dated June 22, 2005. Detailed information about the environmental risk from the ETU degradate may be found in the document and "*Environmental Fate and Ecological Risk Assessment for Ethylenethioureas (ETU) a Common Degradate of the Ethylenebisdithio-carbamate fungicides (EBDCs): Metiram, Mancozeb, and Maneb...(Phase 3 Response),"* dated June 21, 2005. These complete revised environmental risk assessments for mancozeb and ETU may be accessed in the OPP Public Docket (OPP-2005-0176) and on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm. This risk assessment was refined and updated to incorporate comments and additional studies submitted by the registrant. Major changes to the risk assessment include the following:

- toxicological endpoint for chronic avian risk assessment;
- characterization of the mancozeb parent and degradates; and
- clarification of the use patterns for mancozeb.

1. Environmental Fate and Transport

Mancozeb is a high molecular weight polymer composed of repeating single units containing manganese and zinc ions. Mancozeb is nearly insoluble in water, is not expected to volatilize from water, and is not expected to bioconcentrate in fish or aquatic organisms. In the environment, mancozeb is expected to decompose rapidly by hydrolysis, resulting in a suite of residues. EPA has identified the mancozeb active ingredient as mancozeb parent, and the suite

of residues as mancozeb complex, which includes a number of compounds, some of which have a strong affinity for and bind tightly to soil and sediment particles (bound residues). Although mancozeb parent degrades quickly by hydrolysis, the mancozeb complex appears to degrade slowly in the environment, via biodegradation and other fate processes.

The degradate of concern (ETU) is predicted to be susceptible to leaching due to its high solubility and mobility. In the soil environment, ETU lacks stability which can limit its leaching, however, its possible slow and steady formation from mancozeb complex can make it available for leaching at low concentrations. ETU has an aerobic soil half-life of about 3 days; in the absence of data, the aquatic aerobic metabolism half-life was assumed to be about 6 days, or double the soil half life. The measured anaerobic aquatic metabolism half-life, however, is substantially longer (149 days); therefore, ETU may be detected in groundwater. ETU is highly soluble in water (20,000 pPE), highly vulnerable to indirect photolysis (half-life is 1 day), and moderately mobile (288 L/kg). It also has a high vapor pressure, but high solubility reduces the possibility of losses from surface water due to volatilization.

EPA has used the existing environmental fate database for mancozeb to characterize the environmental exposure associated with mancozeb use for a screening-level assessment. The Agency believes that additional data may refine the estimates of environmental exposure but not affect the overall conclusions of the screening-level assessment. As part of this RED, EPA intends to issue a DCI requiring submission of additional environmental fate data for mancozeb parent, the mancozeb complex, and the ETU degradate. These data are expected to confirm the conclusions of this environmental risk assessment.

2. Ecological Risk Assessment

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to nontarget organisms from the use of mancozeb products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). In general, the higher the RQ the greater the concern.

RQ values are compared to the Agency's levels of concern (LOCs), given in Table 33, which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects on nontarget organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to that category. These RQ values may be further refined by characterization of the risk assessment. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. To the extent feasible, the Agency seeks to reduce environmental concentrations in an effort to reduce the potential for adverse effects to nontarget organisms. For a more detailed explanation of the ecological risks posed by the use of mancozeb, refer to "*Environmental Fate and Ecological Risk Assessment for Mancozeb...(Phase 3 Response),"* dated June 22, 2005.

Table 33. EPA's Levels of Concern (LOCs) for Ecological Risks & Risk Presumptions

If the RQ exceeds the LOC value given below...			Then EPA presumes...
Terrestrial Organisms	Aquatic Organisms	Plants	Risk Presumption
0.5	0.5	1	**Acute Risk -** there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification.
0.2	0.1	N/A	**Acute Restricted Use -** there is potential for acute risk, but may be mitigated through restricted use classification.
0.1	0.05	1	**Acute Endangered Species -** endangered species may be adversely affected; regulatory action may be warranted.
1	1	N/A	**Chronic Risk -** there is potential for chronic risk; regulatory action may be warranted.

3. Exposure to Nontarget Organisms

a. Exposure to Aquatic Organisms

EPA considers surface water as the only potential source of exposure to aquatic organisms, since most aquatic organisms are not found in ground water. Surface water models are used to estimate exposure to freshwater aquatic animals. Available monitoring data are generally not from studies targeted on small water bodies and primary streams, where many aquatic animals are found. Although parent mancozeb is highly susceptible to hydrolysis and is not expected to occur in aquatic systems, the hydrolysis product, a suite of related residues (mancozeb complex) is expected to occur. Therefore, the Agency used screening-level modeling to derive estimated environmental concentrations (EECs) for the mancozeb complex in surface water (Table 34).

Table 34. Estimated Environmental Concentrations (EECs) of Mancozeb Complex in Water

Crop/Scenario	Application Rate, Number of Applications, Application Interval	EECs for Mancozeb in Surface Water (ppb)				
		Peak	96-hour Average	21-day Average	60-day Average	Annual Average
Apples (NC)	4.8 lbs ai/A 4 applications 7 day interval	73.4	22.8	7.0	3.2	0.5
Sweet Corn (OR)	1.2 lbs ai/A 15 applications 4 day interval	68.2	24.6	9.6	4.5	1.1
Potatoes (ME)	1.6 lbs ai/A 7 applications 5 day interval	46.8	13.3	4.3	2.2	0.5
Tomatoes (FL)	2.4 lbs ai/A 7 applications 7 day interval	210.8	56.0	16.7	7.3	1.4
Wheat (TX)	1.6 lbs ai/A 3 applications 7 day interval	103.4	29.7	7.7	3.2	0.6

The EEC values used to assess exposure to aquatic animals differ from the values used to assess human exposure from drinking water. Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the index reservoir and percent crop area factor refinements. The index reservoir and percent crop area factor represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. In addition, the drinking water assessment is based on the degradate ETU whereas the aquatic risk assessment is based on modeled EECs for the mancozeb complex.

b. Exposure to Terrestrial Organisms

The Agency assessed exposure to terrestrial organisms by first predicting the amount of mancozeb residues found on animal food items and then by determining the amount of pesticide consumed by using information on typical food consumption by various species of birds and mammals. The amount of residues on animal feed items are based on the Fletcher nomogram (a model developed by Fletcher, Hoerger, Kenaga, et al.), a default half life of 35 days, the current maximum application rate for mancozeb, the maximum number of applications per year (when specified), and the minimum interval between applications. In situations where there is no annual limit on the number of applications, the Agency assumed 3 applications per year. The Agency modeled the maximum and mean residues of mancozeb in various food items immediately after application of mancozeb to representative crops. EPA's estimates of mancozeb residues on various wild animal food items are summarized in Table 35. EPA used these EECs and standard food consumption values to estimate dietary exposure levels for mancozeb to birds and mammals.

Table 35. EECs for Mancozeb on Wild Animal Food Items (from Fletcher Nomogram)

Food Item	EEC (pPE) following 1 application at 1 lb ai/A	
	Predicted Maximum Residue	Predicted Mean Residue
Short grass	240	85
Tall grass	110	36
Broadleaf plants/Insects	135	45
Seeds	15	7

The Mancozeb Task Force voluntarily developed and submitted two studies measuring mancozeb residues in insects and grass in order to refine the Agency's EECs for food items (MRIDs 46392801 and 46392701). These studies are currently undergoing review and were therefore not considered in the RED. However, these data are not expected to significantly change the Agency's conclusions about exposure to terrestrial organisms.

c. Exposure to Nontarget Terrestrial and Aquatic Plants

Nontarget terrestrial and aquatic plants may be exposed to mancozeb from runoff or spray drift from adjacent treated sites. EPA did not evaluate exposure and risk to nontarget terrestrial plants due to deficiencies in the toxicology database for these species. A toxicity study for aquatic plants is a data gap from a previous DCI; data for terrestrial plants will be included in the DCI for this RED. The Agency used the aquatic EECs presented in Table 34 to estimate exposure to nontarget aquatic plants.

4. Environmental Effects (Toxicity)

a. Toxicity to Aquatic Organisms

Mancozeb is considered to have high or very high acute toxicity to fish and aquatic invertebrates. Estuarine/marine invertebrates are the most sensitive, with an acute EC50 of 10.5 ppb. The acute toxicity of mancozeb to aquatic organisms is summarized in Table 36. In addition, the Agency has recently received an acute aquatic toxicity study for mancozeb on rainbow trout (MRID 46161001), which is undergoing review.

Table 36. Acute Toxicity of Mancozeb to Aquatic Organisms

Toxicity Study	Test Species	% a.i.	Endpoint	Toxicity Category	MRID No.
Freshwater					
Fish	Rainbow trout, *Salmo gairdneri*	80	LC_{50} = 460 ppb	Highly toxic	40118502
Invertebrate	*Daphnia magna*	80	LC_{50} = 580 ppb	Highly toxic	40118503
Green Algae	*Selenastrum capricornutum*	82.4	EC_{50} = 47 ppb	Not applicable	43664701
Estuarine/Marine					
Fish	sheepshead minnow, *Cyprinodon variegatus*	82.4	LC_{50} = 1,600 ppb	Moderately toxic	41844901
Invertebrate	mysid shrimp *(Americamysis bahia)*	82.4	EC_{50} = 10.5 ppb	Very highly toxic	41822901

Chronic toxicity studies for mancozeb were conducted for freshwater fish and invertebrates, but not for estuarine/marine species. There is a data gap for chronic aquatic toxicity studies in estuarine/marine fish and invertebrates. Chronic toxicity data for freshwater species are summarized in Table 37 below. In addition, the Agency has recently received chronic toxicity studies for mancozeb on rainbow trout and *Daphnia magna* (MRIDs 46023701 and 46023702), which are under review.

Table 37. Chronic Mancozeb Toxicity to Freshwater Aquatic Organisms

Toxicity Study	Test Species	% a.i.	Endpoint	MRID No.
Fish Early Life Stage	Fathead minnow, *Pimephales promelas*	79.3	NOAEC = 2.19 ppb, LOAEC = 4.56 ppb Survival and lack of growth effects	43230701
Invertebrate Life Cycle	*Daphnia magna*	82.4	21-day NOAEC = 7.3 ppb, LOAEC = 12 ppb; immobility, length, and time until first brood	40953802

b. Toxicity to Terrestrial Organisms

Mancozeb is categorized as slightly to practically nontoxic to avian species and small mammals on an acute oral basis. Avian acute oral toxicity testing was conducted for mancozeb using the English sparrow, mallard duck, and Japanese quail as test species. The acute oral LD_{50} was determined to be ~1500 mg/kg for the sparrow and >6400 mg/kg for the duck and quail. These studies were not the standard single oral dose studies but were multiple oral dose studies that were accepted as supplemental studies in lieu of the standard testing. Therefore, mancozeb is categorized as slightly to practically nontoxic to avian species on an acute oral basis. The acute toxicity profile for birds and mammals is summarized in Table 38.

Table 38. Mancozeb Acute Toxicity Endpoints for Birds and Mammals

Toxicity Study	Test Species	% a.i.	Endpoint	Toxicity Category	MRID No.
Acute (Single dose by gavage)					
Avian Oral	English Sparrow	86	LD50 ~ 1500 mg/kg/day	Slightly toxic	00036094
Mammalian Oral	Laboratory Rat	72.6	LD50 > 5000 mg/kg/day	Practically nontoxic	00142522

Chronic avian reproduction testing was conducted for mancozeb on mallard ducks and bobwhite quails. The lowest No Observable Adverse Effect Concentration (NOAEC) was determined to be 125 pPE on the ducks with a Lowest Observable Adverse Effect Concentration (LOAEC) of 1,000 pPE based upon reductions in the following: egg production; early and late embryo viability; hatchability; and offspring weight at hatch and 14-days of age. Two studies on quail yielded NOAECs of 125 and 300 pPE. The LOAECs for both of these studies was 1000 pPE based upon reductions in the weight of hatchlings and 14-day old survivors and reduction in the number of 14-day old survivors. Results from a rat chronic reproduction study for mancozeb indicate a parental toxicity at a LOAEL of 1,200 pPE and a NOAEL of 120 pPE, with decreased parental body weight, increased relative thyroid weights, and increased incidence of thyroid follicular cell hyperplasia.

Table 39. Mancozeb Chronic Toxicity Endpoints for Birds and Mammals

Test Species	% a.i	NOAEC or NOAEL (pPE)	LOAEC or LOAEL (pPE)	Effects at LOAEC or LOAEL	MRID No.
Chronic Mallard Duck study	80.1	125	1000	Reductions in egg production; early and late embryo viability; hatchability; and offspring weight at hatch and 14-days of age	44159501
Laboratory rat reproductive study	84	120	1200	body wt decrements, increased relative thyroid wt, thyroid follicular hyperplasia in parents	41365201

Nontarget Insects. Available data from a honey bee acute toxicity study indicated that mancozeb is practically non-toxic to the honey bee, with an acute $LD_{50} > 179$ µg/bee (MRID 00018842). However, a study on beneficial mites (*Typhlodromus pyri)* determined a LR_{50} (residue concentration on foliage causing 50% lethality) 0.1 lb a.i./A. The LOAEC for this study is 0.02 lb a.i./A, the lowest concentration tested (MRID No. 45577201).

Terrestrial Plants. Available seedling emergence and vegetative vigor data for a pesticide product containing a mixture of mancozeb and methomorph showed less than 25% inhibition of the growth parameters that were evaluated in these studies (MRID 44283401). However, these studies must be repeated on a typical pesticide product containing mancozeb as the only active ingredient, at the highest application rate, to address the potential toxicological effects from the mixture of active and inert ingredients in the formulated product. These data will be included in the DCI for this RED.

3. Ecological Risks from Mancozeb

a. Risk to Aquatic Organisms

To evaluate mancozeb risk to aquatic organisms, EPA selected representative patterns and modeled maximum application rates and minimum intervals between applications. The agency modeled apples, potatoes, sweet corn, tomatoes, and wheat as surrogate crops to represent the use pattern for mancozeb.

Freshwater organisms. Acute RQs are predicted using peak EECs for the mancozeb complex in surface water, and chronic RQs are predicted using the 60-day mean EECs. For fish, acute RQs range from 0.1 to 0.46 and exceed the LOCs for endangered species. Chronic RQs for freshwater fish range from 1.00 to 3.33 and exceed LOCs. For freshwater invertebrates, acute RQs range from 0.08 to 0.36 and exceed the LOCs for endangered species. Chronic RQs for freshwater invertebrates range from 1.0 to 2.3 and exceed LOCs for sweet corn, tomatoes, and wheat. Acute RQs for algae range from 1 to 4.5 and exceed LOCs for all modeled uses. Mancozeb risks to freshwater aquatic organisms are summarized in Table 40 below.

Table 40. Summary of Mancozeb Risks to Freshwater Aquatic Organisms

Use Site/ Application Method	Application Rate/ # of Apps/Interval	Acute Risk Quotients (RQs) (peak EECs)			Chronic RQs (60 day average EECs)	
		Fish	Daphnia	Algae	Fish	Daphnia
Apples - ground & aerial	4.8 lbs ai/A 4 applications 7 day interval	0.16	0.13	1.56	1.46	0.96
Sweet Corn ground & aerial	1.2 lbs ai/A 15 applications' 4 day interval	0.15	0.12	1.45	2.05	1.32
Potato - ground & aerial	1.6 lbs ai/A 7 applications 5 day interval	0.10	0.08	1.00	1.00	0.59
Tomato - ground & aerial	2.4 lbs ai/A 7 applications 7 day interval	0.46	0.36	4.49	3.33	2.29
Wheat - ground & aerial	1.6 lbs ai./A 3 applications 7 day interval	0.22	0.18	2.20	1.46	1.05

RQs for fish are based on a LC50 of 460 ppb for rainbow trout and a NOAEC of 2.19 ppb for fathead minnow. RQs for daphnia are based on an EC50 of 580 ppb and a NOAEC of 7.3 ppb for water flea, *Daphnia magna*. RQs for algae are based on an EC50 of 47 ppb for green algae, *Selenastrum capricornutum*.

Estuarine/marine organisms. For estuarine/marine fish, acute RQs range from 0.05 to 0.13 and exceed LOCs for endangered species for mancozeb use on apples, tomatoes, and wheat. Acute RQs for invertebrates range from 4.46 to 20.08 and exceed LOCs for all modeled uses. The acute RQs for mancozeb for estuarine/marine organisms are outlined in Table 41 below. The Agency was unable to determine chronic risks for estuarine/marine organisms because there

is a data gap for chronic toxicity studies for these species. These data will be required in the DCI for this RED.

Table 41. Summary of Acute Mancozeb Risks to Estuarine/Marine Organisms

Use Site/ Application Method	Application Rate/ # of Apps/Interval	Acute RQs	
		Fish	Mysid Shrimp
Apples - ground & aerial	4.8 lbs ai/A 4 applications 7 day interval	0.05	6.99
Sweet Corn ground & aerial	1.2 lbs ai/A 15 applications' 4 day interval	0.04	6.5
Potato - ground & aerial	1.6 lbs ai/A 7 applications 5 day interval	0.03	4.46
Tomato - ground & aerial	2.4 lbs ai/A 7 applications 7 day interval	0.13	20.08
Wheat - ground & aerial	1.6 lbs ai./A 3 applications 7 day interval	0.06	9.85

b. Risk to Nontarget Terrestrial Organisms

Acute risks. The Agency does not have a concern for acute risk to nontarget terrestrial organisms for use of mancozeb on crops because mancozeb has low acute toxicity to birds and mammals. EPA also evaluated acute risk to nontarget organisms exposed to treated seeds. RQs for applications of mancozeb treated seed range from 0.00001 to 0.0009 and do not exceed any LOCs. Therefore, the Agency does not have an acute risk concern for mancozeb seed treatment uses.

Chronic Risks. For birds, chronic RQs exceed the LOC for most sites, application rates, and application frequencies considered. Chronic avian RQs range from 0.5 to 35 for diets based on the mean EECs (dietary residues derived from the Fletcher nomogram). The range of RQs given for each commodity represent different animal food items. The highest risk concern is for birds that consume short grass, with RQs for mancozeb use on turf approaching 35. These RQs are conservative screening-level values based on a residue half life of 35 days. Chronic RQs for birds are summarized in Table 42.

Table 42. Chronic Avian RQs for Mancozeb

Use Site/ Application Method	Application Rate/ # of Apps/Interval	Chronic RQs*	
		Based on Maximum EECs	Based on Mean EECs
Turf/ground & aerial (sod farms)	19 lb ai/A 3 apps/year 5 day interval	6-99	3-35
Turf/ground & aerial (golf courses)	17.4 lbs ai/A 3 apps/year 5 day interval	6-91	3-32
Papaya/ground & aerial	4.0 lbs ai/A 7 apps 5 day interval	3-41	1-14
Apple, Crabapple, Pear, & Quince Ground & aerial	4.8 lbs ai/A 4 apps 7 day interval	2-30	1-11
Grapes Ground & Aerial *East of Rockies*	3.2 lbs ai/A 6 apps 7 day interval	2-27	1- 10
Cucumber, Melons, & Squash Ground & Aerial	2.4 lbs ai/A 8 apps 7 day interval	1.5- 24	0.7 - 8
Corn Ground & Aerial *East of Mississippi*	1.3 lbs ai/A 15 apps 4-day interval	1.3 - 21	0.6 - 7.4
Potato & Sugarbeet Ground & Aerial	1.6 lbs ai/A 7 applications 5-day interval	1 - 16	0.5 - 6
Tomato Ground & Aerial *East of Mississippi*	2.4 lbs ai/A 7 applications 7 day interval	1.4 - 22	0.6 - 8

* Chronic avian RQs are based on a NOAEC of 125 pPE from mallard duck study. Chronic RQs are given for both maximum EECs, which represent the upper bound value for mancozeb residues on avian food items and for mean EECs, which represent the arithmetic mean of residues from the Fletcher nomogram.

Chronic RQs for mammals also exceed the LOC for many sites, especially for higher application rates and frequent applications. Chronic mammalian RQs range from 0.5 to 37 for mancozeb (based on mean EECs). Mean EECs represent the arithmetic mean of residues from the Fletcher Nomogram. The range of RQs in a category represent different food items. These RQs are conservative screening-level values based on a default foliar residue half life of 35 days. EPA's greatest risk concerns are for mammals that feed on short grass from mancozeb use on turf and ornamentals at rates > 14 lb ai/A. Chronic risks to mammals are summarized in Table 43.

Table 43. Chronic Mammalian RQs for Mancozeb

Use Site/ Application Method	Application Rate/ # of Apps/Interval	Chronic RQs*	
		Based on Maximum EECs	Based on Mean EECs
Turf/ground & aerial (golf courses)	17.4 lbs ai/A assume 3 apps/year 5 day interval	6- 95	3-34
Turf/ground & aerial (sod farms)	19 lbs ai/A assume 3 apps/year 5 day interval	6.5 - 104	3 - 37
Ornamentals groundcover (Pachysandra)	13.9 lbs ai/A 5 applications 10 day interval	6 - 97	3 - 34
Papaya/ground & aerial	4.0 lbs ai/A 7 apps 5 day interval	3 - 42	1.2 - 15
Grapes Ground & Aerial *East of Rockies*	3.2 lbs ai/A 6 apps 7 day interval	2 - 28	1 - 10
Melons & Squash Ground & Aerial	2.4 lbs ai/A 8 apps 7 day interval	1.6 - 25	0.7 - 9
Corn Ground & Aerial *East of Mississippi*	1.2 lbs ai/A 15 apps 4-day interval	1.4 - 22	0.6 - 8
Potato & Sugarbeet Ground & Aerial	1.6 lbs ai/A 7 applications 5-day interval	1 - 17	0.5 - 6
Tomato Ground & Aerial *East of Mississippi*	2.4 lbs ai/A 7 applications 7 day interval	1.4 - 23	0.7 - 8

Mammalian RQs are based on a NOAEL of 120 pPE based on rat 2-generation reproductive toxicity study.
*Chronic RQs are given for both maximum EECs, which represent the upper bound value for mancozeb residues on mammalian food items and for mean EECs, which represent the arithmetic mean of residues from the Fletcher Nomogram.

Nontarget Insects. Because available data show that mancozeb is practically non-toxic to honeybees, the Agency does not have a risk concern for nontarget insects.

Nontarget Terrestrial Plants. The Agency was unable to conduct a risk assessment for nontarget terrestrial plants due to a data gap for terrestrial plant toxicity data. These data will be included in the DCI for this RED.

5. Ecological Risks from ETU

The Agency conducted an ecological risk assessment for the ETU degradate of mancozeb and the other EBDC fungicides, maneb, and metiram. EPA chose to model ecological risks from ETU based on mancozeb because it has the broadest use pattern of the EBDC fungicides. Modeling based on mancozeb would therefore allow the Agency to conduct a thorough, comprehensive evaluation of potential risks from ETU. The Agency's ecological risk assessment for ETU is summarized below. Specific details may be found in the document *"Environmental Fate and Ecological Risk Assessment for ETU. ...(Phase 3 Response)*," dated June 21, 2005.

a. ETU Risk to Aquatic Organisms

Limited data are available on the toxicity of ETU to aquatic organisms; however, the available data show that ETU has low acute toxicity to aquatic organisms. ETU is practically nontoxic to cold water fish and slightly toxic to freshwater invertebrates. Toxicity endpoints used in the aquatic risk assessment for ETU are given in Table 44 below. No acute toxicity data were available for estuarine/marine organisms. In addition, the Agency has recently received additional data for ETU. These studies, chronic toxicity studies for *Daphnia* (MRIDs 46462901 and 46462903) and acute toxicity studies for rainbow trout (MRID 46462902) and freshwater algae (46462904), are undergoing review.

Table 44. Acute Toxicity of Ethylenethiourea (ETU) to Freshwater Aquatic Organisms

Toxicity Study	Test Species	% a.i.	Endpoint	Toxicity Category	MRID No. or Other Reference
Fish	rainbow trout *(Oncorhynchus mykiss)*	99.9	LC50 > 502 pPE	Practically nontoxic	45910401 45020903 Zok 2001
Invertebrate	*Daphnia magna*	99.6	LC50 = 26.9 pPE	Slightly toxic	45910402 46020901
Algae	green algae *(Pseudokirchneriella subcapita)*	99.6	EC50 = 23 pPE; NOEC = 12.5	Not applicable	45910403 46020902 Reuschenbach 2000

The Agency used modeling to estimate the exposure of aquatic organisms to ETU. EPA used the Tier II PRZM-EXAMS model to calculate EECs of ETU in surface water. The Agency used the peak EECs with the ETU acute toxicity endpoints to calculate RQs for aquatic organisms exposed to ETU. RQs for fish, invertebrates, and plants were far below the Agency's level of concern. Therefore, for the organisms for which toxicity data are available, EPA does not have a risk concern for aquatic organisms exposed to ETU.

b. ETU Risk to Terrestrial Organisms

Birds. The Agency has no data on the acute or chronic toxicity of ETU to birds. Therefore, EPA is currently unable to evaluate the acute or chronic risk to birds exposed to ETU. However, the Agency is requiring the necessary toxicity data as part of the DCI for this RED.

Mammals. The Agency does not expect a significant acute risk from ETU to mammals. ETU is practically nontoxic to mammals, with a mouse acute oral LD_{50} of 2,300 mg/kg. In addition, no adverse effects to terrestrial organisms have been reported for the parent EBDCs or ETU. Because ETU is practically nontoxic to mammals on an acute basis and there are no documented incidents linking the parent EBDCs or ETU to adverse effects in mammals, EPA does not believe there is an acute risk concern and therefore did not calculate acute RQs for mammals.

The Agency relied on guideline toxicity studies on rodents for information on the chronic toxicity of ETU to mammals. EPA chose an endpoint from a developmental toxicity study in rats for the chronic risk assessment for mammals; that study is summarized in Table 45.

Table 45. Chronic Reproductive Toxicity Endpoint for Mammals

Toxicity Study	Test Species	% a.i.	Endpoint	MRID
developmental toxicity	rat	not reported	NOAEL is 5 mg/kg/day; LOAEL is 10 mg/kg/day for developmental effects of the brain	45937601

Chronic risks to mammals vary according to the type of diet consumed and the EEC for ETU in each food item. The chronic RQs for ETU were calculated only for maximum EECs because the RQs are based on a single dose developmental toxicity study, rather than the longer term reproductive toxicity study used to calculate the chronic RQs for mancozeb. Use of mean EECs would result in lower RQs. Mammals who are granivores, subsisting on a diet of seeds or grain, do not have risks of concern from ETU exposure. Granivores have chronic RQs ranging from 0.01 to 0.48 based on maximum EECs. The chronic risks for this value are not presented in detail in this document, but may be found in the document, "*Environmental Fate and Ecological Risk Assessment for ETU....(Phase 3 Response),"* dated June 21, 2005. However, for herbivores and insectivores, mammals that subsist on a diet of plants and insects, predicted RQs based on maximum EECs indicate the potential for chronic risks of concern from ETU.

For small mammals feeding on short grass, chronic RQs range from 37 from the use of mancozeb on turf to 3.1 for use on ornamentals (other than pachysandra). For small mammals feeding on forage and small insects, chronic RQs range from 21 from mancozeb turf applications to 2 from mancozeb vegetable applications. For medium sized mammals feeding on short grass, ETU's chronic RQs range from 26 for turf to 2 on vegetables. For medium sized mammals feeding on forage and small insects, ETU's potential RQs exceed LOCs for all uses of mancozeb. For medium sized mammals feeding on forage and small insects, the RQs range from 14 for turf applications of mancozeb to 1 on vegetables. For large mammals feeding on short grass, RQs range from 6 on turf to 1 on bananas. EPA does not have a chronic risk concern for

large mammals from use of mancozeb on sugar beet, fennel, peanuts, forestry (douglas fir), Christmas tree plantations, tobacco, cotton, asparagus, garlic & shallot, ornamentals, barley and small grains, or vegetables. For large mammals feeding on forage and small insects, the predicted ETU RQs exceed the level of concern only for use of mancozeb on apples, papaya, pachysandra (an ornamental groundcover), and turf.

Table 46. Summary of Chronic Mammalian Exposures and Risks (RQs) from ETU

Use Site/Application Method	Application Rate Number of Applications Application Interval	Maximum Estimated Environmental Concentrations (EECs) for Different Diets, mg/kg			Range of Risk Quotients (RQs) for Different Diets		
		Short Grass	Forage & Small Insects	Large Insects	Short Grass	Forage & Small Insects	Large Insects
Apple - ground & aerial	4.8 lbs ai/A 4 apps 7 day interval	61	34	4	1.8 - 11.5	1 - 6.5	0.1 - 0.7
Banana & Plantain - ground & aerial	2.4 lbs ai/A 10 applications 14 day interval	36	20	2	1.1 - 6.8	0.6 - 3.8	0.07 - 0.4
Corn - ground & aerial *East of Mississippi*	1.2 lb ai/A 15 apps 4 day interval	42	24	3	1.3 - 8	0.7 - 4.5	0.08 - 0.5
Cucumber - ground & aerial	2.4 lbs ai/A 8 applications 7 day interval	48	27	3	1.4 - 9.1	0.8 - 5.1	0.1 - 0.6
Grapes - Ground & aerial *East of Rockies*	3.2 lb ai/A 6 applications 7 day interval	54	30	3	1.6 - 10.2	0.9 - 5.7	0.1 - 0.6
Melons & Squash - ground & aerial	2.4 lbs ai/A 8 applications 7 day interval	48	27	3	1.4 - 9.1	0.8 - 5.1	0.1 - 0.6
Onion, Garlic, & Shallot - ground & aerial	2.4 lbs ai/A 10 applications 7 day interval	53	30	3	1.6 - 10.2	0.9 - 5.7	0.1 - 0.6
Papaya - ground & aerial	4 lbs ai/A 7 applications 7 day interval	81	46	5	2.4 - 15.5	1.4 - 8.7	0.2 - 1
Potato & Sugar Beet - ground & aerial	1.6 lbs ai/A 7 applications 5 day interval	33	18	2	1 - 6.2	0.6 - 3.5	0.06 - 0.4
Tomato - ground & aerial	2.4 lbs ai/A 7 applications 7 day interval	44	25	3	1.3 - 8.4	0.8 - 4.7	0.08 - 0.5
Ornamentals - ground & aerial	1.6 lbs ai/A 3 applications* 7 day interval	187	105	12	0.5 - 3.1	0.3 - 1.7	0.03 - 0.2

Use Site/Application Method	Application Rate Number of Applications Application Interval	Maximum Estimated Environmental Concentrations (EECs) for Different Diets, mg/kg			Range of Risk Quotients (RQs) for Different Diets		
		Short Grass	Forage & Small Insects	Large Insects	Short Grass	Forage & Small Insects	Large Insects
Pachysandra - ground	14 lbs ai/A 5 applications 10 day interval	187	105	12	5.6 - 35	3.2 - 20	0.4 - 2.2
Turf (golf course) - ground	17.4 lbs ai/A 3 applications* 5 day interval	182	102	11	5.5 - 34.6	3.1 - 19.5	0.3 - 2.2
Turf (sod farms)	19 lbs ai/A 3 applications 5 da interval	199	112	12	6 - 37.8	3.4 - 21.3	0.4 - 2.4

* Maximum number of applications not specified for this crop. EPA assumed 3 applications.

Insects. The parent EBDCs are nontoxic to honeybees from short-term exposure. Further, EPA does not expect significant ETU exposure to honeybees in flight or to bees foraging on plants for pollen or nectar. Therefore, the Agency does not have a risk concern for honeybees or other nontarget insects.

Plants. The Agency has no data on the toxicity of ETU to terrestrial plants, and limited data on the parent EBDCs. Therefore, the Agency did not conduct a risk assessment for ETU on terrestrial plants. EPA is requiring additional data on terrestrial plants for the parent compound and will reserve similar data requirements for ETU until the data for the parent compounds have been received and reviewed.

6. Ecological Incidents

Several reports of wildlife poisonings are associated with mancozeb. The Agency's Ecological Incident Information System reports mancozeb in three fish kill incidents occurring in 1970, 1992 and 1995. In the 1970 and 1992 incidents, mancozeb had been applied with insecticides highly toxic to fish (thiodan and endosulfan) and, because of sample analysis, EPA classified mancozeb as unlikely to have been responsible for the these fish kills. The third incident in 1995 involved an accidental mancozeb spill into a stream that was the source water for a salmon hatchery which resulted in a fish kill at the salmon hatchery. Although no samples of either fish or water were analyzed, the Agency considered mancozeb to be a probable cause to the kill. In another incident, a 1992 bird kill on an island off the coast of France, mancozeb was applied with methomyl, an insecticide highly toxic to birds. Although the Agency classified mancozeb as a possible contributor to this incident, it is more likely that methomyl caused the kill. In another incident, where mancozeb was tank mixed with benomyl and applied to apple trees, leaves and blossoms dropped from the trees. Identical applications made to apple orchards by other growers in the area did not result in this damage; the Agency classified mancozeb as a possible contributor in this incident. Ecological poisoning incidents associated with mancozeb are summarized in Table 47 below. Additional information about the Agency's classification

and interpretation of ecological incidents may be found in the document, "*Environmental Fate and Ecological Risk Assessment for Mancozeb...(Phase 3 Response)*," dated June 22, 2005.

Table 47. Summary of Ecological Poisoning Incidents for Mancozeb.

Incident Number	Pesticide(s) Involved	Date (month/year)	Adverse Effect	Magnitude of Damage
B0000-501-42	Mancozeb & benomyl	Unknown	Plant damage	not reported
B0000-233	Mancozeb, sulfur, & thiodan	7/1970	Fish kill	thousands
I006382-002	Mancozeb & methomyl	9/1972	Bird kill	- 35 birds killed - 31 intoxicated - involved green finches, gold finches, and linnets
I000799-008	Mancozeb, maneb, fenarimol, & endosulfan	4/1992	Fish kill	> 600 fish
I008745-004	Mancozeb	7/1995	Fish kill	30,000 to 35,000 fish

7. Risk to Federally Listed Endangered and Threatened Species

Available screening-level information for mancozeb indicate a potential concern for chronic effects on listed species of birds and mammals, acute and chronic effects on listed species of freshwater fish and freshwater invertebrates, and acute effects on listed species of estuarine/marine fish should exposure actually occur. Although the RQs for estuarine/marine invertebrates and nonvascular aquatic plants exceed the Agency's level of concern, there are no federally listed species in these taxa.

EPA does not currently have enough data to quantify risks for mancozeb at the screening level and therefore cannot preclude potential direct effects to the following taxonomic groups: aquatic and terrestrial plants and estuarine/marine organisms (chronic effects). These findings are based solely on EPA's screening-level assessment and do not constitute "may effect" findings under the Endangered Species Act for any listed species.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened 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 considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, this analysis will consider regulatory changes recommended in this RED that are being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any

potential effects, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as appropriate. If the Agency determines that the use of mancozeb "may affect" listed species or their designated critical habitat, EPA will employ provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is complete, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposure to mancozeb at levels of concern.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing mancozeb as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing mancozeb.

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 mancozeb. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient mancozeb, the Agency has sufficient information on the human health and ecological effects of mancozeb 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 mancozeb containing products are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of mancozeb 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 mancozeb, 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.

Based on its evaluation of mancozeb, the Agency has determined that mancozeb 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 mancozeb. If all changes outlined in this document are incorporated into the product labels, then all current risks for mancozeb 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 III. B.6. of this document.

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 mancozeb. During the public comment period on the risk assessments, which closed on February 22, 2005, the Agency received comments from registrants, commodity/grower groups, cooperative extension specialists, and grower/commodity groups. These comments in their entirety and the Agency's response are available in the public docket (OPP-2004-0078) at http://www.epa.gov/edockets.

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 sources only) exposure to mancozeb is within its own "risk cup." An aggregate assessment was conducted for exposures to mancozeb through food, drinking water, residential, and recreational uses (golf courses). Because mancozeb and the other EBDC fungicides (maneb and metiram) degrade to ETU in the environment and metabolize to ETU in the body, the aggregate assessment included ETU derived from mancozeb and the other EBDCs. The Agency has determined that the human health risks from these combined exposures to both mancozeb and ETU are within acceptable levels. In other words, EPA has concluded that the tolerances for mancozeb meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from mancozeb and ETU.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for mancozeb, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of mancozeb. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of mancozeb and its ETU metabolite and degradate. EPA has also considered information on the toxicity of ETU, and the aggregate exposure to ETU, resulting both from the use of mancozeb and from the use of the other EBDC fungicides.

As discussed in Section III, the total acute and chronic dietary (food alone) risks from mancozeb are not of concern. Aggregate risk from mancozeb, mancozeb-derived ETU, and ETU from all sources are not of concern provided that mitigation measures outlined in this document are adopted and labels are amended. The aggregate risk assessment for ETU includes residential scenarios, because mancozeb and maneb both have uses that may result residential exposure, and both degrade to ETU.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for mancozeb, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the 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 the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of mancozeb residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of mancozeb, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. On the basis of this information, the Special FQPA Safety Factor has been removed (i.e., reduced to 1X) for mancozeb *per se.* In addition, the Agency determined whether infants and children show potential susceptibility from exposure to residues of ETU, a metabolite and degradate of mancozeb and the other EBDCs. Although the Special FQPA Safety Factor was removed (reduced to 1X) for ETU, a 10X FQPA database uncertainty factor was retained to address the lack of a developmental neurotoxicity study, rabbit developmental, and comparative thyroid studies. The rationale for the decisions on FQPA safety factors and database uncertainty factors for both mancozeb and ETU is explained in detail in Section III of this document.

2. 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).

The available human health and ecological effects data for mancozeb suggest possible endocrine effects. Mammalian studies for mancozeb showed thyroid effects, which may indicate potential endocrine disruption. EPA has considered these effects in the human health risk assessment by selecting endpoints based on thyroid effects. To further characterize these effects, EPA is requiring a confirmatory comparative thyroid toxicity study for ETU. Mancozeb data on ecological effects suggest possible hormonal effects to birds and mammals. When the

appropriate screening and/or testing protocols being considered under the EDSP have been developed, mancozeb may be subject to additional screening and/or testing.

3. Cumulative Risks

The FFDCA, as amended by 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. For the purposes of this reregistration eligibility decision, EPA has concluded that mancozeb does not share a common mechanism of toxicity with other substances. The Agency reached this conclusion after a thorough internal review and external peer review of the data on a potential common mechanism of toxicity. EPA concluded that the available evidence does not support grouping the EBDC fungicides based on a common toxic effect (neuropathology) occurring by a common mechanism of toxicity (metabolism to carbon disulfide). For more information, please see the December 19, 2001 memo, *"The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity*"on the internet at http://www.epa.gov/oppsrrd1/cumulative/dithiocarb.pdf.

D. Tolerance Reassessment Summary

Tolerances for residues of mancozeb in/on plant, animal, and processed commodities are established under 40 CFR §180.176 and §180.319. Mancozeb tolerances are currently expressed as mancozeb *per se*, a coordination product of zinc ion and maneb (manganous ethylene-bisdithiocarbamate) containing 20% manganese, 2.5% zinc, and 77.5 % ethylene-bisdithiocarbamate and calculated as zinc ethylenebis dithiocarbamate (or zineb).

The Agency is proposing that the mancozeb tolerance expression be revised to include the residues of mancozeb only, calculated as CS_2, rather than zineb, which has no active registrations. This will update the CFR to include only those EBDC fungicides with current registrations, and will also allow the Agency to harmonize with CODEX. The proposed tolerance expression for mancozeb under 40 CFR §180.176 is as follows:

> Tolerances are established for residues of a fungicide that is a mixture of 5.2 parts by weight of ammoniates of [ethylenebis(dithiocarbamato)]zinc with 1 part by weight ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides, *calculated as carbon disulfide, CS_2,* in or on raw agricultural commodities.

As a result of changes to the list of raw agricultural and processed commodities and feedstuffs derived from crops provided in OPPTS Guideline 860.1000, mancozeb tolerances must be revoked for certain raw agricultural commodities which are no longer considered livestock feed items. Also, some commodity definitions must be corrected in accordance with

current Agency practices. The forty four (44) existing tolerances for mancozeb have been reassessed.

1. Tolerances Currently Listed Under 40 CFR §180.176(a)

Adequate residue data have been submitted to reassess the established tolerances for the following commodities, as defined: apples; asparagus; bananas; barley, grain; barley, straw; carrots; corn, fodder; corn forage; corn, grain (except popcorn grain); corn, fresh including sweet corn, kernels plus cobs with husks removed (K+CWHR); corn, pop, grain; crabapples; cranberries; cucumbers; fennel; grapes; melons; oats, grain; oats, straw; onions (dry bulb); papayas, whole fruit; peanuts; pears; quinces; rye, grain; rye, straw; squash, summer; sugar beets; sugar beet tops; tomatoes; wheat, grain; and wheat, straw. Label amendments are required to change the PHI for small grains, to provide specific instructions for aerial application to orchard crops, to restrict against the feeding of peanut hay to livestock, to limit use of mancozeb on field corn to hybrid seed corn, and to remove the feeding/grazing restrictions for corn.

Additional confirmatory residue data are necessary to reassess the established tolerance for cottonseed, and a ruminant feeding study is necessary to reassess the tolerances for kidney and liver. Additional data are required for celery as a condition for a full registration decision.

The established tolerance for peanut hay should be revoked because the Agency allows label restrictions against the feeding of peanut hay to livestock. If, in the future, additional registrations are sought on peanuts, the Agency will ensure that peanut hay feeding restrictions are included on the label.

According to the revised commodity descriptions in Table 1 of OPPTS Guideline 860.1000, the processed commodities of oats are flour and groats/rolled oats. Therefore, the established tolerance for bran of oats should be revoked.

The established tolerance for the milled feed fractions of barley, oats, rye, and wheat should be revoked, and individual tolerances for the processed commodities of cereal grains will be reassigned under 40 CFR §180.176(a) pending the outcome of the requested processing studies.

2. Tolerances to Be Proposed Under 40 CFR §180.176(a)

After many of the tolerances for livestock food items were originally established, the Agency changed the commodity descriptions as well as the commodities for which livestock feedstuff tolerances are required. These modifications were necessary to address changes in livestock feeding practices. Most of the changes in this section are as a result of this policy.

Adequate residue data have been submitted (or were translated) for the establishment of mancozeb tolerances for the following commodities: barley, bran; barley, flour; beet, sugar, pulp, dried; flax, seed; oat, flour; rice, grain; rice, straw; rye, bran; rye, flour; sorghum, grain; sorghum, stover; wheat, bran; wheat, flour; and wheat, short. In addition, adequate residue data have been submitted (or were translated) for the establishment of mancozeb tolerances to support

seed treatment uses for the following commodities: flax seed; rice grain and straw; and sorghum grain, forage, and stover. Additional seed treatment data and tolerances are required for safflower.

Additional residue data are necessary to establish mancozeb tolerance values for the following commodities: barley hay; cotton, gin byproducts; oat, hay; and wheat hay. The requested data for wheat hay will be translated to barley hay and oat hay. However, because the Agency has no dietary, drinking water, residential, or aggregate risk concerns for these tolerances, they are considered reassessed.

Tolerances for oat forage, rye forage, and wheat forage are not required because the period in which these small grains are "foraged" is prior to the time growers would make fungicide applications; therefore, no residues would be expected in the forage.

A tolerance for the aspirated grain fractions of field corn is not required because of nondetectable residues observed during the field corn grain study (conducted at 1x application rate) and marginal concentration of residues from the corn processing study (conducted at 5x application rate). A tolerance for the aspirated grain fractions of wheat is also not required because mancozeb is registered for use on wheat during the early vegetative stage and/or before the reproduction stage begins and seed heads are formed.

Additional bridging processing data are required for barley (pearled barley), oats (groats/rolled oats), and wheat (middlings and germ). The Agency will assess the need for tolerances on these processed commodities when the requested studies have been submitted and evaluated.

3. Tolerances Listed Under 40 CFR §180.176(b)

The temporary tolerance on ginseng associated with the FIFRA §18 Emergency Exemptions for this commodity should be reassigned under 40 CFR §180.176(a) pending a future decision on establishing a permanent ginseng tolerance. Adequate data residue data are available to support a permanent tolerance for ginseng.

4. Tolerances To Be Reassigned Under 40 CFR §180.176(c)

Once the subpart D petition for carrot and celery regional registrations has been addressed, the established tolerances for carrots and celery, presently listed under 40 CFR §180.176(a), should be reassigned under 40 CFR §180.176(c) for the purpose of tolerance reorganization. The registrants are only supporting regional registrations for mancozeb uses on carrots grown in Florida, Michigan, and Wisconsin, and on celery grown in Florida.

5. Tolerances Listed Under 40 CFR §180.319

The interim tolerance for potatoes listed under 40 CFR §180.319 should be reassigned as a permanent tolerance under 40 CFR §180.176(a). Adequate residue data are available to support the reassignment of interim potato tolerance (established at 1.0 ppm) to a permanent tolerance (reassessed at 0.2 ppm).

Table 49. Tolerance Reassessment Summary for Mancozeb.

Commodity	Established Tolerance (ppm mancozeb *per se*)	Reassessed Tolerance (ppm CS_2)	Comment *[Correct Commodity Definition]*
Tolerance Listed Under 40 CFR §180.176(a) Raw Agricultural Commodities			
Apples	7	0.6	Available data support lowering tolerance. *[Apple]*
Asparagus	0.1 (negligible residue)	0.1	
Bananas	4 (preharvest use only) 0. 5 pulp (no peel)	2	Available data support lowering tolerance. *[Banana]*
Barley, grain	5	1	Available data for wheat grain support lowering barley tolerance. Contingent upon requested label revision.*
Barley, milled feed fractions	20	Revoke	
Barley, straw	25	20	Available data for wheat straw support lowering barley tolerance. Contingent upon requested label revision.*
Carrots	2	1	Available data support lowering tolerance. Storage stability data must be submitted. Tolerance should be reassigned to 40 CFR §180.176(c) pending Subpart D decision on regional registration.
Celery	5	2	Available data support lowering tolerance. Storage stability data must be submitted. Tolerance should be reassigned to 40 CFR §180.176(c) pending Subpart D decision on regional registration.

Commodity	Established Tolerance (ppm mancozeb *per se*)	Reassessed Tolerance (ppm CS_2)	Comment *[Correct Commodity Definition]*
Corn, fodder	5	Reassign	Tolerance should be reassigned concomitant with establishing a 15 pPE tolerance for *[Corn, field, stover]* and a 40 pPE tolerance for *[Corn, sweet, stover]*.
Corn, forage	5	Field corn forage 40	Contingent upon label revision to remove feeding/grazing restrictions. Tolerance should be reassigned concomitant with establishing a 40 pPE tolerance for [Corn, field, forage]
		Sweet corn forage 70	Contingent upon label revision to remove feeding/grazing restrictions. Tolerance should be reassigned concomitant with establishing a 70 pPE tolerance for [*Corn, sweet, forage*]
Corn, grain (except popcorn grain)	0.1	0.06	Contingent upon limiting use of mancozeb on hybrid seed corn type only. [*Corn, field, grain*]
Corn, fresh including sweet corn (K+CWHR)	0.5	0.1	[*Corn, sweet kernel plus cob with husks removed*]
Corn, pop, grain	0.5	0.06	Available data for sweet corn (kernel plus cob with husks removed) support lowering tolerance.
Cottonseed	0.5	TBD	Tolerance to be established pending EPA determination on finite residues from seed treatment use.
Crabapples	10	0.6	Available data for apples support lowering tolerance. *[Crabapple]*
Cranberries	7	5	Available residue data support lowering tolerance. *[Cranberry]*
Cucumber	4	Reassign	Tolerance should be reassigned concomitant with establishing a crop group tolerance for *[vegetable, cucurbit, group 9]*.
Fennel	10	2.5	Available data for celery support lowering tolerance.
Grapes	7	1.5	Available residue data support lowering the tolerance *[Grape]*
Kidney	0.5	TBD	TBD pending submission of ruminant feeding study (OPPTS GDLN 860.1480).

Commodity	Established Tolerance (ppm mancozeb *per se*)	Reassessed Tolerance (ppm CS_2)	Comment *[Correct Commodity Definition]*
Liver	0.5	TBD	TBD pending submission of ruminant feeding study (OPPTS GDLN 860.1480).
Melons	4	Reassign	Tolerance should be reassigned concomitant with establishing a crop group tolerance for *[vegetable, cucurbit, group 9]*.
Oat, bran	20	Revoke	No longer considered a significant livestock feed item (GDLN OPPTS 860.1000)
Oat, grain	5	0.6	Available data for wheat grain support lowering the tolerance. *[Oat, grain]*
Oat, milled feed fractions	20	Revoke	
Oat, straw	25	20.0	Available data on wheat straw support lowering tolerance. *[Oat, straw]*
Onions (dry bulb)	0.5	1.5	Available residue data support raising the tolerance. *[Onion, bulb]*
Papayas, whole fruit	10, with no residue present in edible pulp after the peel is removed and discarded	9	*[Papaya]*
Peanuts	0.5	0.1	*[Peanut]*
Peanut vine hay	65	Revoke	Revoke pending amendment of product labels to include the following feeding restriction: "Do not feed green immature growing plants to livestock or do not harvest for livestock feed."
Pears	10	0.6	Available residue data support lowering the tolerance *[Pear]*
Quinces	10	0.6	Available residue data for pears support lowering tolerance. *[Quince]*
Rye, grain	5	0.6	Available residue data for wheat grain support lowering tolerance. Contingent upon requested label revision.*
Rye, milled feed fractions	20	Revoke	
Rye, straw	25	20	Available residue data for wheat straw support lowering the tolerance.
Squash, summer	4	Reassign	Tolerance should be reassigned concomitant with establishing 2 pPE tolerance for *[vegetable, cucurbit, group 9]*.

Commodity	Established Tolerance (ppm mancozeb *per se*)	Reassessed Tolerance (ppm CS_2)	Comment *[Correct Commodity Definition]*
Sugar beets	2	1.2	Available residue data support lowering the tolerance. *[Beet, sugar, roots]*
Sugar beet, tops	65	60	Available residue data support lowering the tolerance. *[Beet, sugar, tops]*
Tomatoes	4	2.5	Available residue data support lowering the tolerance. *[Tomato]*
Wheat, grain	5	1	Available residue data support lowering the tolerance . Contingent upon requested label revision.*
Wheat, straw	25	25	Harmonized with Codex data
Tolerances To Be Proposed Under 40 CFR §180.176(a) Raw Agricultural Commodities			
Barley, hay	None	TBD	TBD pending submission of field trial data for wheat hay (OPPTS GDLN 860.1500).
Barley, bran	None	2.0	Available data for wheat bran support establishing a tolerance.
Barley, flour	None	1.2	Available data for wheat flour support establishing a tolerance.
Beet, sugar, pulp, dried	None	3.0	*[Beet, sugar, dried pulp]*
Cotton, gin byproducts	None	TBD	TBD pending submission of field trial data (OPPTS GDLN 860.1500).
Curcubit Crop Group	None	2	*[Vegetable, cucurbit, group 9]*
Flax, seed	None	0.15	
Oats, hay	None	TBD	TBD pending submission of field trial data for wheat hay (OPPTS GDLN 860.1500).
Oat, flour	None	1.2	Available data for wheat flour support establishing a tolerance.
Pineapple	None	TBD	TBD pending submission of additional data.
Rice, grain	None	0.06	
Rice, straw	None	0.15	
Rye, bran	None	2.0	Available data for wheat bran support establishing a tolerance.
Rye, flour	None	1.2	Available data for wheat flour support establishing a tolerance.
Safflower, seed	None	TBD	TBD pending submission of field trial data for seed treatment (OPPTS GDLN 860.1500).

Commodity	Established Tolerance (ppm mancozeb *per se*)	Reassessed Tolerance (ppm CS_2)	Comment *[Correct Commodity Definition]*
Sorghum, forage	None	0.15	*[Sorghum, grain, forage]*
Sorghum, grain	None	0.25	*[Sorghum, grain, grain]*
Sorghum, stover	None	0.15	*[Sorghum, grain, stover]*
Wheat, hay	None	TBD	TBD pending submission of field trial data for wheat hay (OPPTS GDLN 860.1500).
Wheat, bran	None	2.0	
Wheat, flour	None	1.2	
Wheat, milled feed fractions	20	Revoke	
Wheat, short	None	2.0	*[Wheat, shorts]*
Tolerance Listed Under 40 CFR §180.176(b) Temporary Tolerances for FIFRA Section 18 Emergency Exemptions			
Ginseng	2.0	1.2	Should be reassigned as permanent tolerance pending decision on FIFRA Section 3 registration. *[Ginseng]*
Tolerances To Be Proposed Under 40 CFR §180.176(c) Regional Registrations			
Carrot	None	0.6	Pending Agency decision on petition to establish regional registration. Storage stability data must be submitted.
Celery	None	2.0	Pending Agency decision on petition to establish regional registration. Storage stability data must be submitted.
Interim Tolerance Listed Under 40 CFR §180.319			
Potatoes	1.0	0.2	Interim tolerance should be reassigned as a permanent tolerance under 40 CFR 180.176(a). [*Potato*]

***** Product labels must be amended to change the PHI from 26 days to "Feekes Growth Stage 10.5 (typically 35-45 days) but no less than 26 days."

6. Codex Harmonization

There are no established or proposed Codex MRLs for residues of mancozeb *per se*; however, Codex limits for dimethyl dithiocarbamates fungicides are grouped under dithiocarbamates. The maximum residue limits (MRLs) for dithiocarbamates are established for several commodities resulting from the use of mancozeb, maneb, metiram, proline, thiram, and ziram and are currently expressed as parts per million carbon disulfide. Currently, no Codex MRLs are established nor have prior MRLs been revoked for residues of ETU for any

commodity. The Agency recommends that the EBDC tolerances be harmonized with Codex with regard to the regulated residue.

7. Residue Analytical Methods - Plants and Livestock (GLN 860.1340)

The reregistration requirements for residue analytical methods are fulfilled for plants only. The analytical methods converting all EBDCs and some metabolites to carbon disulfide are considered adequate for enforcement of tolerances in plant commodities, along with a specific method for ETU. However, a validated analytical method for tolerance enforcement in animal commodities is still needed. The Agency recommends the Onley gas chromatography (GC) method (AOAC 14th Edition 29.119:554) for determination of ETU residues. In addition to the enforcement methods, acceptable data collection methods have been used in analyzing field trial and monitoring samples for EBDC and ETU residues. The Agency recommends that the data collection method for EBDC residues be included in *Pesticide Analytical Methods* (PAM) Volume II as an alternate enforcement method.

Mancozeb and ETU are not recovered using any FDA Multiresidue Protocols (specifically, Multiresidue Protocol A-E and 232.3). The October 1999 *Pesticide Analytical Methods* (PAM, Volume I, Appendix I) indicates ETU is not recovered using method Sections 303 (Mills, Onley, and Gaither method; Protocol E), and 304 (Mills method for fatty food); however, there is a small recovery (<50%) of ETU using multiresidue method Section 302 (Luke method; Protocol D).

E. Regulatory Rationale

The following is a summary of the rationale for mitigation measures necessary for managing risks associated with the use of mancozeb for mancozeb to be eligible for reregistration. Where labeling revisions are warranted, specific language is set forth in the summary table of Section V (Table 51 of this RED document).

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

Acute and chronic dietary (food only) risk do not exceed the Agency's level of concern for the U.S. general population and all population subgroups, including infants and children, using highly conservative assumptions. Risk estimates for both acute and chronic exposure are less than 100% of the aPAD or cPAD. Furthermore, the dietary cancer risk for mancozeb-derived ETU in food is within the negligible risk range of 1×10^{-6} for the general US population. Therefore, no mitigation is needed.

b. Drinking Water Risk Mitigation

The drinking water exposure assessment for mancozeb addresses concentrations of ETU only. Mancozeb is not expected to remain in water long enough to reach a location that would supply drinking water for human consumption, whether from surface or groundwater. The estimated DWECs for ETU are low and not of concern. Therefore, no mitigation is needed for drinking water.

c. Residential Risk Mitigation

To mitigate risk concerns for toddlers who may be playing on transplanted sod previously treated with mancozeb, a 3-day prohibition on harvesting is necessary to prevent mancozeb application to turf 3 days prior to harvest of sod. The Mancozeb Task Force has agreed to this measure. To further address residential post-application exposure from turf, the Task Force has agreed to voluntarily delete all use of mancozeb on residential lawns from pesticide product labels. The Agency published a *Notice of Receipt* of these (and other) use deletions in the June 1, 2005, *Federal Register* and intends to issue a cancellation order to implement these use deletions.

To mitigate risk concerns for adults exposed to mancozeb from treated turf on athletic fields, the Mancozeb Task Force has agreed to delete the use of mancozeb on turf on athletic fields, and submitted a request for deletion of this use, in letters to the Agency dated August 26 and August 29, 2005. The Agency intends to publish a *Notice of Receipt* of this use deletion in the *Federal Register* in September, 2005. In addition, the use of mancozeb on athletic field turf is not eligible for reregistration.

d. Aggregate Risk Mitigation

As discussed in Section III of this document, aggregate risk refers to the combined risk from food, drinking water, and residential exposures. In addition, aggregate risk can result from one-time (acute), short-term and/or chronic exposures. Below is a discussion of the risk for each duration of exposure and any risks of concern.

1) Acute Aggregate Risk

Acute aggregate risk from food and drinking water is below the Agency's level of concern for both mancozeb-derived ETU and ETU from all sources. For mancozeb-derived ETU, the modeled peak EDWC of 25.2 ppb ETU in surface water is below the acute DWLOC of 123 ppb and is therefore not of risk concern. Acute dietary exposure to ETU from all sources

comprises 87% of the aPAD at the 99.9th percentile of exposure, and is not of risk concern. Therefore, no mitigation is necessary.

2) Short-Term Aggregate Risk

Mancozeb Aggregate. The short-term aggregate MOEs for mancozeb for residential handlers using mancozeb in home gardens are significantly greater than 100 and therefore not of concern. No mitigation is necessary.

ETU Aggregate. The short-term aggregate risk for ETU includes chronic dietary and drinking water exposures combined with short-term exposure as a result of residential or recreational uses of mancozeb. In all cases, the aggregate short-term ETU MOEs are significantly greater than 1000 and not of risk concern to the Agency. Therefore, no mitigation is necessary.

3) Chronic (Non-Cancer) Aggregate Risk

Chronic aggregate risk for ETU includes dietary exposure from food and water. For mancozeb-derived ETU, the highest estimated exposure from food and drinking water comprises 34% of the cPAD for children 1-2 years old, the most highly exposed population subgroup. For ETU from all sources, exposure from food and drinking water comprises 58% of the cPAD for children 1-2 years old. Therefore, chronic aggregate risk from ETU is below the Agency's level of concern and no mitigation is needed.

4) Aggregate Cancer Risk

Aggregate cancer risk estimates for from mancozeb-derived ETU are in the range of 1×10^{-6}, and aggregate cancer risks from ETU from all sources are in the range of 2×10^{-6}. EPA believes that these risk estimates are in the negligible risk range and therefore do not require mitigation.

e. Occupational Risk Mitigation

It is the Agency's policy to mitigate occupational risk to the greatest extent practical and feasible. Mitigation measures may include reducing application rates, adding personal protective equipment (PPE) to end product labels, requiring the use of engineering controls, and other measures. A wide range of factors is considering in making risk management decisions for worker risks. These factors include, in addition to the estimated MOEs and cancer risk estimates, incident data, the nature and severity of adverse effects observed in animal studies, uncertainties in the risk assessment, alternative registered pesticides, the importance of the chemical in integrated pest management (IPM) programs, and other similar factors.

1) Handler Exposure

Handler exposure assessments are completed by EPA considering the use of baseline PPE, and, if warranted, increasing levels of PPE and engineering controls are considered in order to estimate their potential impact on exposure and risk. For mancozeb and mancozeb-derived ETU, the target MOE for workers is 100 based on information provided in Section III of this document. For occupational cancer risks, risk estimates in the general range of 1×10^{-6} do not exceed the Agency's level of concern. When occupational MOE are less than 100 or occupational cancer risks exceed the general range of 1×10^{-6}, EPA strives to reduce worker cancer risks through the use of personal protective equipment and engineering controls or other mitigation measures. The Agency considers occupational cancer risks in the general range of 1×10^{-6} or less to be negligible, but may accept risks as high as 1×10^{-4} when all mitigation measures that are practical and feasible have been applied, particularly when there are critical pest management needs associated with the use of the pesticide. Levels of PPE considered and applicable to the proposed mitigation are described below:

- Baseline - long-sleeved shirt, long pants, and shoes and socks
- Single layer - baseline plus gloves
- Double layer - baseline plus gloves and coveralls
- PF5 - a dust/mist filtering respirator
- PF10 - a half face respirator with appropriate cartridges

The Agency also considered engineering controls for some exposure scenarios. These include the following: water soluble pack for WP; closed capture dust collection system for seed and seed-piece treatment; and closed cabs for groundboom, airblast, or aerial application

The Agency analyzed the handler risks for mancozeb and mancozeb-derived ETU and concluded that the greatest risk concerns predicted were from mancozeb-derived ETU. Both chronic, noncancer risks and cancer risks of concern were predicted for mancozeb-derived ETU, with MOEs less than 100 and cancer risks greater than 1×10^{-6}. In most cases, mitigation measures addressing cancer risks of concern also address any chronic noncancer risks.

Handler Mitigation for Turf, Ornamentals, and Agricultural Crops. The highest handler risks were predicted for mixing and loading activities with wettable powder formulation; these ranged from 3.3×10^{-7} to 1.7×10^{-4} with double layer PPE and a PF 5 respirator. Chronic MOEs range from 28 to >1000. Handler risks were lower for other mancozeb formulations, including dry flowables and liquids. Therefore, the Agency determined mitigation measures based on both formulation type and crop groups. These are described in detail below and summarized in Table 50.

Formulation Specific Mitigation - Wettable Powder (WP)

Turf. To mitigate handler risks associated with this use, the registrants have agreed to package the WP formulation in water soluble bags, and limit its use on turf to golf courses and

industrial parks. The WP formulation will no longer be used on sod farms. The Agency believes that these measures will mitigate handler risk concerns. Cancer risk estimates after mitigation are in the 10^{-7} range and chronic MOEs are >1000, and not of concern.

Ornamentals. To mitigate handler risks from this use, the WP labels must require the following personal protective equipment (PPE): single layer (long sleeve shirt, long pants, shoes, and socks) with gloves and a PF 5 dust-mist respirator. The Agency believes that these measures will adequately mitigate handler risk concerns. Cancer risk estimates are in the negligible risk range ($\leq 1.4 \times 10^{-6}$) when mitigation measures are considered.

Agricultural Crops. To mitigate handler risks from this use, the WP labels must require the following personal protective equipment PPE: single layer with gloves and a PF 5 dust-mist respirator. The Agency believes that these measures will mitigate handler risk concerns to the extent feasible. Cancer risk estimates for handlers wearing single layer PPE, gloves and a PF respirator are in the range of 1×10^{-6} for groundboom, airblast, and hand application (e.g. hand wand). For aerial application and chemigation, cancer risks are in the 10^{-5} range and the chronic MOE for small grains, cotton, and cucurbits is 89 with the PPE described above. EPA believes that the respirator requirement for the WP formulation will have a positive effect in reducing potential exposures, resulting in a gradual shift in the industry to the safer DF formulation.

Formulation Specific Mitigation - Dry Flowable (DF)

Turf, Ornamentals, and Agricultural Crops. To mitigate handler risks associated with the DF formulation, the DF labels must require the following PPE:

- Mixer/loaders -single layer + gloves
- Applicator, all methods except aerial & groundboom - single layer + gloves
- Applicator, aerial, airblast, and groundboom - single layer, no gloves.

Handlers who are applying pesticide through from a closed cab airplane, with closed cab airblast equipment, or with a closed cab tractor pulling a groundboom, do not need to wear gloves in the cab to avoid contaminating the cab. The Agency believes that these mitigation measures will address handler risk concerns to the extent feasible. With this PPE, cancer risks are in the 10^{-6} range for all crops except turf, which has a cancer risk estimate in the 10^{-5} range. As previously mentioned, the Agency believes that the DF formulation poses significantly lower risks overall than the WP. Also, EPA expects that the PPE/engineering control requirements associated with the WP formulation, compared with the less restrictive PPE on the DF formulation, will have a positive effect in reducing potential exposures, resulting in a gradual shift in the industry to the safer formulation.

Formulation Specific Mitigation - Liquids

Turf. For aerial application and chemigation, cancer risks for handlers are in the 10^{-5} range with single layer PPE and in the high 10^{-6} range with single layer PPE, gloves, and a PF 5

respirator. To mitigate this risk concern, mancozeb registrants have agreed to disallow aerial and chemigation application for golf course use. Registrants have also agreed to disallow aerial application to sod farms, but will retain chemigation on sod farms. Product labels must require workers to wear single layer PPE and gloves and a PF 5 respirator. Estimated handler risks for chemigation are in the range of 9×10^{-6}.

Ornamentals and Agricultural Crops. To mitigate handler risks associated with the liquid formulations, labels for the liquid formulation must require the following PPE:

- Mixer/loaders -single layer + gloves
- Applicator, all methods except aerial & groundboom - single layer + gloves
- Applicator, aerial, airblast, and groundboom - single layer, no gloves.

Handlers who are applying pesticide through a closed cab airplane, with closed cab airblast equipment, or with a closed cab tractor pulling a groundboom do not need to wear gloves in the cab to avoid contaminating the cab. The Agency believes that these PPE will mitigate handler risk concerns. Cancer risk estimates for handlers are in the negligible risk range ($\leq 3 \times 10^{-6}$) when these PPE are considered.

Table 50. Summary of Worker (Handler) Mitigation for Turf, Ornamentals, and Agricultural Crops

Formulation/Application Method Typical Crop(s)	Mitigation Measures	Short-Intermediate Term Inhalation MOE with this Mitigation	Cancer Risk with this Mitigation
Mixer/Loaders (M/L)			
WP Aerial Application or Chemigation turf - sod farms	Use Deleted from WP Label	Not applicable	Not applicable
WP Aerial Application or Chemigation All other crops	Single layer + PF 5 Respirator	89- 410	5.6 x 10-5
WP Groundboom Sod Farms	Use Deleted from WP Label	Not applicable	Not applicable
WP Groundboom Golf Courses	Engineering controls (Water Soluble Pack)	>500	7 x 10-7
WP Groundboom all other crops	Single layer + PF 5 Respirator	440 - >1000	1.4 to 9.3 x 10-6
WP Airblast tree fruits & grapes	Single layer + PF 5 Respirator	670 - >1000	1.7 to 3.6 x 10-6
WP for Turfgun Turf	Single layer + PF 5 Respirator	>1000	2.5 x 10-6
WP HP Handwand Pachysandra	Use Deleted from WP labels	Not applicable	Not applicable
DF Aerial or Chemigation Turf (sod farms)	Single layer w/ gloves	> 310	2.7 x 10-5
DF Aerial or Chemigation All other crops	Single layer w/gloves for chemigation Single layer no gloves for aerial	≥ 1400	1.9 to 8.5 x 10-6

Formulation/Application Method Typical Crop(s)	Mitigation Measures	Short-Intermediate Term Inhalation MOE with this Mitigation	Cancer Risk with this Mitigation
DF Groundboom, Airblast, Turfgun, or HP Handwand turf (sod farms)	Single layer w/gloves	≥ 1400	6.1 x 10-6
DF Groundboom, Airblast, Turfgun, or HP Handwand All other crops	Single Layer w/gloves	≥ 1400	2.1 x 10-7 to 1.1 x 10-6
Liquids Aerial Application or Chemigation Turf (sod farms)	Aerial application will be deleted from label Single layer w/gloves for chemigation	≥ 200	9×10^{-6}
Liquids for Aerial Application or Chemigation All other crops	Single layer w/ gloves	≥ 200	1.7 to 7.8 x 10-6
Liquids for Groundboom, Airblast, Turfgun or HP Handwand Turf (sod farms)	Single layer w/ gloves	≥ 880	5.6 x 10-6
Liquids for Groundboom, Airblast, Turfgun or HP Handwand All other crops	Single layer w/ gloves	≥ 880	1.3 x 10-6 to 4.6 x 10-8

Formulation/Application Method Typical Crop(s)	Mitigation Measures	Short-Intermediate Term Inhalation MOE with this Mitigation	Cancer Risk with this Mitigation
Applicators			
Aerial Application Turf (sod farms)	Use Deleted from all Labels	Not Applicable	Not Applicable
Groundboom Application Other Crops	Single layer, no gloves	≥ 1400	< 1 x 10-6
Airblast Application Other Crops	Single layer, no gloves	≥ 1300	1.7 to 8.4 x 10-7
Turfgun Application Turf (sod farms)	Single layer w/ gloves	>1000	3.1 x 10-6
HP Handwand Application Ornamentals	Single layer w/ gloves	> 1000	4 x 10-6 t0 9 x 10-7
Mixer/Loader/Applicators (M/L/A)			
M/L/A WP with Low Pressure Handwand pachysandra, conifers, ornamentals	Pachysandra Use Deleted from all labels Single layer w/ gloves for other ornamentals	>1000	2 - 4 x 10-6
M/L/A WP with Turfgun Turf	Single layer w/ gloves	>1000	2 x 10-5
M/L/A DF with Turfgun Turf	Single layer w/ gloves	270	not assessed
M/L/A Liquids with LP Handwand ornamentals	Single layer w/ gloves	> 1000	5.6 x 10-7
M/L/A Liquids Backpack Sprayer ornamentals	Single layer w/ gloves	≥ 8700	≤ 1 x 10-6
M/L/A Liquids Turfgun Turf	Single layer w/ gloves	>1000	2.4 x 10-6
MOEs for Flagger			

Formulation/Application Method Typical Crop(s)	Mitigation Measures	Short-Intermediate Term Inhalation MOE with this Mitigation	Cancer Risk with this Mitigation
Flag Aerial Spray Applications all crops above	Prohibit human flaggers Require mechanical flaggers	Not Applicable	Not Applicable

Handler Mitigation for Seed and Seed-Piece Treatment. Pesticide handlers who are loading dusts and wettable powders for commercial seed and seed-piece treatment have chronic MOEs ranging from 15 to 59 with baseline protective clothing (i.e., single layer, no gloves). These same handlers also have cancer risks ranging from 5.9×10^{-5} to 3.7×10^{-4}. Handler risks (MOEs and cancer risks) are not of concern for the other formulations used; i.e., liquids and dry flowables.

To mitigate the handler risks for potato seed-piece treatment with dusts and wettable powder formulations, the Agency is requiring engineering controls (closed capture equipment) for commercial seed-piece treatment and additional PPE (single layer, gloves, and PF 5 respirator) for noncommercial, on-farm seed-piece treatment. When these mitigation measures are considered, handler risk cancer estimates are in the 10^{-7} range for both on-farm and commercial seed- piece treatment. The mancozeb registrants have agreed to these mitigation measures.

To mitigate handler risks for seed treatment with dusts and the WP formulation, registrants have agreed to require engineering controls (dust collection equipment). With this mitigation, cancer risk estimates for workers are in the negligible risk range (10^{-6}) and not of concern. Registrants have also agreed to place specific use directions on all WP labels used for seed treatment. (These are detailed in the label table in Section V of this document.)

Workers involved in packaging treated seeds, i.e., those who do not have direct contact with mancozeb, do not have risks of concern when baseline PPE are worn. This also applies to workers involved in planting treated seeds or seed pieces. For these workers, a single layer of clothing without gloves (baseline PPE) provides adequate protection. The registrants have agreed to this mitigation.

f. Post-Application Risk Mitigation

As previously mentioned, the Agency mitigates worker cancer risks to the extent feasible, striving to mitigate MOEs to 100 and cancer risks to the general range of 1×10^{-6}. However, the Agency may accept estimated risks in the range of 10^{-4} to 10^{-6} when all practical and feasible measures have been implemented, particularly when there are critical pest management needs associated with the pesticide and certain re-entry activities.

Because of the concern for cancer risk to re-entry workers at several days after application, EPA and its regulatory partner, USDA, Office of Pest Management Policy, contacted land grant universities, regional IPM centers, and grower groups to obtain additional information about post-application worker activities and maximum feasible REIs. The goal of this exercise was to determine when high contact, high exposure, and high risk activities were performed relative to mancozeb application and to collect other information about mancozeb use that might factor into the regulatory decision on REIs for this RED. The agencies' findings are given in the summary paragraphs for specific crops.

When preparing post-application risk assessments, EPA considers dislodgeable foliar residue (DFR) data, application rates, transfer coefficients based on crop type and exposure scenario (low, medium, or high contact activities), and assumptions about average occupational workdays and adult body weight. In the case of mancozeb, both mancozeb and its degradate ETU were considered in the assessment. For the ETU cancer risk assessment, the Agency assumed that workers conducting post-application activities would be exposed for 30 days each year.

Chronic ETU MOEs for post-application workers are greater than 100 on the day of application for all scenarios. Therefore, the Agency does not have risk concerns for chronic noncancer risks, and no mitigation is needed for these risks. However, cancer risk estimates for re-entry workers range from 4×10^{-7} to 4×10^{-5} on the day of mancozeb application for high contact activities.

Available DFR data for mancozeb show that residues on foliage degrade slowly. As a result, predicted cancer estimates also decrease slowly over time. For several high-end exposure scenarios, risk to re-entry workers is in the range of 5×10^{-6} on the day of application. Long REIs are impractical for mancozeb because it is a fungicide that must be applied repeatedly for efficacy. In addition, cultural practices for many crops require re-entry within a day of mancozeb application. Therefore, the Agency plans to maintain the current 24 hour REI for many crops based on the advantages of the use of this chemical in fungal disease resistance management.

Apples. For re-entry workers performing high-contact activities, such as pruning, training, tying, and thinning after mancozeb application to apples, cancer risk estimates are in the 10^{-5} range for several days after application. Worker cancer risk estimates for low and very low contact activities, such as irrigating, scouting, and placement of phermone traps, are in the 10^{-6} range and 10^{-7} range, respectively. EPA consulted the USDA apple pest management strategic plan and other sources to determine the timing of mancozeb application relative to various re-entry activities. These sources show that summer pruning and other high contact activities do not start until at least 2 weeks after mancozeb application. However, growers need to re-enter orchards to place phermone traps and monitor irrigation equipment. Therefore, the 24 hour REI will be maintained.

Bananas. Re-entry cancer risk estimates on the day of application are as high as 6×10^{-6} for high-contact activities, such as hand harvesting. At the current REI of 24 hours, the cancer risk for high contact activities is 5.4×10^{-6}. According to the University of Hawaii, worker re-entry activities must be performed daily and an REI longer than 24 hours is not feasible. Because banana plants at all stages of development exist within a field, re-entry activities are varied, and include pruning, deflowering, bagging, harvesting, and bunch spraying. The 24 hour REI will be maintained.

Christmas Trees. Mancozeb is used to control fungal diseases in seedling nurseries and needle cast in more mature trees. High contact worker re-entry activities for Christmas tree

production include harvesting, bagging, and tying, and are limited to mature trees. Sheering, which is considered a medium contact activity, does not occur in seedling nurseries, and is generally done at least a month after mancozeb is applied to more mature trees for control of needle cast. Therefore, the Agency does not have a risk concern for re-entry activities for Christmas trees, even though calculated worker re-entry cancer risks are in the 10^{-5} range.

Cranberries. The Agency estimated cancer risks only for low contact re-entry activities, such as applying fertilizer, scouting, weeding, raking, and mulching for cranberries. There are no high contact re-entry activities associated with cranberry production. The cancer risk estimate for re-entry workers is 5×10^{-6} on the day of application and 4.3×10^{-6} at 1 day post-application. Mancozeb is applied to cranberries during fruit set, to control fruit rot. Fertilizer must be applied at about the same time, when the canopy is dry. Therefore, the 24 hour REI will be maintained.

Cucurbits (Cucumbers, Melons, and Squash). For both high and medium contact activities, cancer risk estimates for re-entry workers are in the range of 10^{-6} for several days after mancozeb application. These activities include hand harvesting, pulling, leaf thinning, turning mature vines back into the row, irrigation, scouting, and weeding mature plants. Many of these activities must be performed frequently during the growing season. Cucumbers and summer squash are harvested daily during peak production. Therefore, the REI will remain at 24 hours.

Grapes. For re-entry workers performing high-contact activities, such as thinning, pruning, training, and tying, cancer risk estimates are in the 10^{-5} range for several days after mancozeb application. Cancer risk estimates for low and medium contact activities are in the 10^{-6} range. According to the National Grape Cooperative, mancozeb and the other EBDCs are typically applied to grapes during the time interval between bud break and blossom, and growers must re-enter vineyards within 48 hours. Typical re-entry activities during that time include suckering, cluster thinning, fertilizer application, and weed management. According to Cornell University, Geneva Experiment Station, the maximum feasible REI for grapes is 24 hour due to intensive canopy and crop management activities that involve hand labor. Cornell states that mancozeb is a mainstay of disease management programs in grapes, with regular applications at 7 or 10 day intervals from bud break until the 66 day PHI has been reached.

Cut Flowers. As previously mentioned, EPA has a risk concern for re-entry workers who are harvesting greenhouse grown cut flowers and similar specialty crops used in the floral industry. On the day of mancozeb application, the chronic MOE for re-entry workers is 170 and the cancer risk estimate is 6.2×10^{-6}. To address this risk concern, the registrants have agreed to limit the number of times mancozeb may be applied to greenhouse cut flowers and other greenhouse grown ornamental crops, such as orchids and ferns, to 20 applications per year. Current labels do not limit the number of times mancozeb may be applied. The Agency believes that this will mitigate the risk concern for re-entry workers. Therefore, the 24 hour REI will be maintained.

Field and Row Crops (cotton, fennel, small grains, sugar beets). On the day of application, for re-entry workers performing high contact activities after application of mancozeb to low growing field and row crops, the cancer risk estimate is 5×10^{-6}. However, the Agency has learned that high contact activities, such as hand harvesting, are not performed for most of these crops. Only fennel is hand harvested. The cancer risk estimate for re-entry workers performing medium contact activities on the day of application is 2.7×10^{-6}, and one day after application, the cancer risk estimate is 2.5×10^{-6}. Because these risk estimates are in the negligible risk range, EPA believes that the existing 24 hour REI is sufficient to address risk concerns. This REI will therefore be maintained.

Papaya. For re-entry workers performing high contact activities, such as hand harvesting, the cancer risk estimate is 1.7×10^{-5} at the current REI of 24 hours, and the cancer risk estimate is 1.1×10^{-5} at 7 days after application. To address this concern, the registrant has lowered the application rate from 4 to 2 lbs ai/A. With the lower rate, cancer risk is 1.8×10^{-5} on the day of application. The current REI cannot be extended beyond 24 hours because of the need for daily harvesting. Mancozeb is used on papaya to control fruit rot caused by anthracnose (*Colletotrichum*) and *Phytophthera*. Papayas are commercially grown in Florida and Hawaii, and fruit is hand harvested. In Florida, harvesting frequency varies from less than once a week to 2 or 3 times per week. In Hawaii, harvesting frequency varies from 1 to 3 times a week. The 24 hour REI will be maintained.

Potato. For medium contact activities, cancer risk estimates for re-entry workers are in the range of 10^{-6} for several days after mancozeb application. The only high contact activity for potatoes is hand harvesting, which is not relevant because this only occurs after the last mancozeb application, after the potato plants are sprayed with desiccant. Most potatoes are harvested mechanically. Medium contact activities include irrigation and scouting mature plants. Mancozeb is important in controlling late blight and may be applied 3 days prior to harvest in a few states, 14 days prior to harvest for other states. This PHI will also prevent high contact activities by re-entry workers. Therefore, the 24 hour REI will be maintained.

Tomato. The Agency has a low risk concern for re-entry workers performing high-contact activities after mancozeb application. Estimated cancer risks are in the negligible risk range of 1×10^{-6} (1.8×10^{-6} on the day of application and 1.6×10^{-6} one day after application). In addition, daily re-entry is critical for fresh market crop grown in Florida and California, the two states with the greatest tomato production. Therefore, the 24 hour REI will be maintained.

Turf. To mitigate post-application risks associated with mancozeb use on turf, the registrants have agreed to establish a 3 day PHI, which effectively creates a 3 day REI for harvesting, which is the highest contact and highest risk activity for reentry workers. This 3 day PHI also mitigates toddler risk from playing on treated turf transplanted to residential lawns.

2. Management of Risks to Nontarget Organisms from Mancozeb

The Agency's policy is to mitigate ecological risks to the greatest extent practical and feasible. Mitigation measures may include lowering application rates, reducing the number of applications allowed in a year, restricting the timing of applications, extending the time between applications (application interval), and changing pesticide use to minimize runoff or spray drift potential. In some situations, registrants may choose to delete certain uses or application methods to address ecological risk concerns.

The screening-level environmental risk assessment for mancozeb suggests acute risk concerns for freshwater fish and invertebrates, estuarine/marine fish and invertebrates, and aquatic nonvascular plants. The environmental risk assessment for mancozeb also suggests that exposure could result in chronic risks of concern to nontarget birds, mammals, and freshwater fish and invertebrates. The risk assessment for ETU suggests chronic risk concerns for mammals. The Agency has addressed these risk concerns to the extent feasible while considering the factors listed above. Specific risk mitigation measures are described in the following sections.

a. Aquatic Organisms

EPA's screening-level risk assessment for mancozeb suggests a slight risk concern for freshwater fish and invertebrates. Acute RQs for fish and invertebrates exceed the screening levels of concern for endangered species. Chronic RQs for fish and invertebrates slightly exceed the screening level of concern. Acute RQs for algae also slightly exceed screening levels of concern for all scenarios.

The Agency's screening-level assessment also suggests acute risk concerns to estuarine/marine invertebrates, with RQs ranging from 4.46 to 20.1. Acute RQs for estuarine/marine fish exceed the levels of concern for endangered species. EPA is unable to evaluate chronic risks to estuarine/marine organisms at this time due to a data gap. These data are required as part of this RED.

The registrant has agreed to some mitigation measures to address risks to aquatic organisms. These include some label changes to minimize non-target spray drift and the several changes to products labeled for use on turf. (These are described in detail in section IV.2.b. below.) The changes to the mancozeb turf label, as well as the deletion of the turf use on residential lawns, are expected to reduce runoff to surface water bodies, thereby reducing risks to fish and aquatic invertebrates.

b. Terrestrial Organisms (Birds and Mammals)

The Agency does not have an acute risk concern for nontarget birds and mammals. Therefore, no mitigation is needed to address acute risks. However, EPA's screening-level risk assessment shows chronic RQs for birds and mammals that exceed the Agency's level of

concern. The screening-level assessment is based on maximum EECs and a default half-life value of 35 days.

Birds. The greatest risk concern is for birds exposed to mancozeb residues on turf; RQs based on mean EECs range from 3 to 32 for use on golf courses and from 3 to 35 for all other turf uses. To mitigate avian risks from the use of mancozeb on turf, registrants have agreed to increase the time between applications from 7-10 days on current labels to 10-14 days and to limit the number of applications allowed per year. In addition, the registrants have agreed to reduce the maximum rate on turf from 19 lbs ai/A to 17.4 lbs ai/A. Also, as previously mentioned, the registrants have voluntarily deleted the turf use on residential lawns from all mancozeb product labels.

EPA also has a chronic avian risk concern associated with other mancozeb uses, including papayas and ornamentals (especially pachysandra). To mitigate risks from the papaya use, mancozeb registrants have agreed to reduce the application rate from 4 to 2 lbs ai/A and change the number of applications. This is expected to reduce the screening-level RQs based on maximum EECs from 41 to 31. RQs based on mean EECs are < 10. As previously mentioned, these high end, screening-level risk estimates are based on a default half life value of 35 days. To mitigate the risk concern for the ornamental use, registrants have requested that their registrations be amended to delete the pachysandra use from all labels.

Mammals. The Agency has a chronic risk concern for small mammals that potentially consume mancozeb residues on food items. The RQs are associated with mancozeb use on turf (3-37) and pachysandra (3-34), an ornamental groundcover, and are based on mean EECs. To mitigate these risks, the mancozeb registrants have agreed to several changes to products labeled for use on the turf. Registrants have also requested that their registrations be amended to delete the pachysandra use from all labels. Other label changes, such as the reduction in rates and number of applications for papaya, are also expected to reduce predicted risks to mammals.

c. Nontarget Insects

Available data show that mancozeb is practically nontoxic to honeybees. The Agency does not have a risk concern for nontarget insects. Therefore, no bee precautionary labeling is required on product labels for mancozeb.

d. Nontarget Terrestrial and Aquatic Plants

Due to a data gap for terrestrial plants, the Agency was unable to conduct a risk assessment at this time. However, plant toxicity studies to address this data gap are required as part of this RED. EPA has a slight risk concern for aquatic plants because the screening-level risk assessment shows that RQs for algae exceed the level of concern. The mitigation measures previously described are expected to reduce spray drift and runoff, thereby addressing the risk concern for aquatic plants.

3. Management of Risks to Nontarget Organisms from ETU

a. Risk Mitigation for Aquatic Organisms

EPA does not have a risk concern for freshwater aquatic organisms exposed to ETU. Acute RQs for freshwater fish, invertebrates, and plants are all far below EPA's screening level of concern. The Agency was unable to conduct an acute risk assessment for estuarine/marine organisms due to data gaps. The necessary data will be included in the generic DC I for this RED. No mitigation is necessary at this time.

b. Risk Mitigation for Terrestrial Organisms

The Agency has no data on the acute or chronic toxicity of ETU to birds and is therefore unable to evaluate any potential risk to birds exposed to ETU as a result of the use of mancozeb or the other EBDC fungicides. To address this data gap, the Agency will require the necessary data in the DCI for this RED.

The Agency does not have an acute risk concern for mammals exposed to ETU because of its low acute toxicity. Further, EPA does not have a chronic risk concern for granivores exposed to ETU. Therefore, no mitigation is necessary for either of these scenarios.

EPA has a chronic ETU risk concern for small mammals feeding on short grass, with chronic RQs based on maximum EECs ranging from 1 to 38. Use of mean EECs would result in lower RQs. The highest RQs are associated with mancozeb use on turf and pachysandra, an ornamental groundcover. EPA believes that the mitigation measures previously described for turf will address risk concerns to the extent feasible. The registrants have agreed to voluntarily cancel the use of mancozeb on pachysandra to address that risk concern in a letter dated August 26, 2005.

4. Significance of Mancozeb and the EBDCs in Agriculture

As previously mentioned, the Agency received many comments in response to the Federal Register Notice published on November 24, 2004 (OPP-2004-0078) announcing the availability of the EBDC risk assessments and requests for risk reduction options. The majority of the comments supported the continued use of the EBDC products and data supporting the usefulness of the EBDCs to control plant diseases. The Agency also obtained information from internal expertise, USDA's Office of Pest Management and Policy, land grant universities, cooperative extension, and proprietary sources on several use sites.

Based on information from a variety of sources, EPA has determined that the EBDC fungicides are particularly important to integrated pest and disease management programs because they are used to delay the development of resistance by fungal plant pathogens to the newer lower risk fungicides. As previously noted, the EBDCs have a multi-site mode of action, which means they disrupt cell metabolism at several sites in the target disease organism, and are

therefore not susceptible to development of resistant disease strains. Because of these characteristics, the EBDCs are important resistance management tools, partner chemicals for tank mixing or rotation with newer and lower risk fungicides that have a single-site mode of action such as the sterol inhibitors and the strobilurins. This property helps to prolong the life of the newer and lower risk fungicides. Mancozeb synergizes with copper fungicides to enhance their efficacy in the control of bacterial diseases, thus extending the life of copper as a bactericide. This property is important in controlling diseases in tomatoes and other vegetables grown for fresh market.

The Agency is committed to long-term pest resistance management strategies, and an important pesticide resistance management strategy is to minimize the number and frequency of applications of pesticides with the same or similar target site of action in the same field (OPP PR Notice 2001-5). Because of this, the Agency has considered the advantages from the use of EBDCs as an important tool in fungicide resistance management programs while making its reregistration decision for all 3 EBDCs, mancozeb, maneb, and metiram.

Further, comparing the cost per treatment of EBDCs with other fungicides, cost information demonstrated that the EBDCs are generally lower. The following paragraphs are summaries for specific use sites.

Apples. Mancozeb, maneb, and metiram are registered to control several important fungal diseases on apples, including scab. The key alternatives to EBDCs include captan, sterol inhibitors, and benzimidazoles. Copper, ziram, cyprodinil, and strobilurins (e.g., trifloxystrobin) are also used. However, none of these fungicides are considered to be a universal substitute for the EBDC fungicides. Fungal resistance to dodine, sterol inhibitor fungicides and benzimidazoles has developed, reducing the ability of these systemic fungicides to control apple diseases in orchards.

Horticultural oil is used to decrease early season mite populations. This early mite population control reduces the total number of miticide applications needed during the course of the apple growing season. The advantage of mancozeb and metiram compared to captan is that captan cannot be used with horticultural oil because this combination is phytotoxic to apple foliage. This phytotoxicity is not seen with mancozeb and metiram. Thus, indirectly, the use of EBDC fungicides in lieu of captan typically reduces the total number of miticide applications needed.

Bananas. Mancozeb may be applied to bananas up to 10 times a year at an average cost of $8.18 per application. The alternative azoxystrobin costs more (at $13.70 per application) and is limited to 8 applications per year to avoid development of resistant fungal strains (Docket OPP-2004-0078, *Ethylenebisdithio-carbamate Fungicides - Benefits to United States Agriculture*). Fungal diseases in bananas can cause reduction in growth, premature ripening of fruit, and significant yield loss. These diseases are controlled either by alternating applications of

mancozeb and/or chlorthalonil with systemic fungicides or by using mancozeb in combination with systemic fungicides (in tank mixes) (Marin et al. 2003).[1]

Cucurbits. Mancozeb is used to control alternaria leaf spot, anthracnose, downy mildew, and gummy stem blight. The major alternatives to mancozeb are chlorothalonil and the strobilurins. As with other crops, mancozeb is used in rotation with the strobilurins to prevent and manage resistance of gummy stem blight to azoxystrobin. Chlorothalonil causes phytotoxicity to watermelon rinds.

Grapes. Mancozeb is important in disease management programs for wine grapes in the East and Midwest, with applications every 7 or 10 days from bud break until the 66 day PHI is reached. Mancozeb is used to control black rot, bunch rot, deadarm, and downy mildew. Alternatives include captan, strobilurins, ziram, ferbam, and mefanoxam. As previously mentioned, the strobilurins are prone to resistance and must be rotated with other fungicides, such as the EBDCs. Captan cannot be tank mixed with oil due to phytotoxicity concerns. The sterol inhibitors have some issues with powdery mildew resistance. Copper is also used, but can damage foliage in sensitive grape varieties (e.g., Concord, Niagra). Cornell, Penn State, and the University of Virginia recommend mancozeb for control of black rot and downy mildew.

Papaya. Mancozeb is used on papaya to control anthracnose (Colletotrichum), powdery mildew, and Phytophthera diseases (fruit rot and root rot). Papaya are commercially grown in Florida and Hawaii. Registered alternatives to control of some of these diseases include azoxystrobin; potassium bicarbonate, sulfur, copper; chlorothalonil; neem oil, mefanoxam (Ridomil Gold), and maneb, which is another EBDC fungicide. Azoxystrobin is the only alternative considered effective for at least the two of the main target diseases (anthracnose, powdery mildew). Currently copper is tank-mixed with mancozeb for control of Phytophthora. Since azoxystrobin is likely to encounter pest resistance problems its use is limited and requires rotation with another effective fungicide (e.g., mancozeb). Mefanoxam is used for certain Phytophthora diseases and is likely to encounter pest resistance problems, unless used in conjunction with another effective fungicide (e.g., mancozeb). According to the University of Hawaii, chlorothalonil is not used on papaya grown for export because of phytotoxicity concerns and worker skin irritation problems. Exported fruit must undergo vapor-heat quarantine treatment which scalds those fruit treated with chlorothalonil. Neem oil is not as effective as mancozeb for anthracnose and works only when disease pressures are low. The efficacy of other alternatives is either uncertain or less than mancozeb.

Potatoes. Mancozeb, maneb, and metiram are used to control early blight and late blight as well as fungi identified in potato seed-piece decay. The alternative products include strobilurins (e.g. azoxystrobin, trifloxystrobin), chlorothalonil, propamocarb, dimethomorph, cymoxanil, copper, triphenyltin hydoxide (TPTH), iprodione, and fluazinam. However, there is

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[1] Douglas Marin et al. 2003. *Black Sigatoka: An Increasing Threat to Banana Cultivation*.Plant Disease Vol 87, No. 3: 208-222.

no one alternative fungicide registered to control all the potato diseases for which EBDCs are registered. There has been reduced sensitivity of the strobilurins towards early blight on potatoes in some areas, managed by requiring rotational applications of strobilurins with fungicides with a different mode of action after every application.

Along with the EBDCs, chlorothalonil has been considered the standard early blight and late blight treatments for years. However, EBDCs are needed when the seasonal allowance of chlorothalonil per acre has been reached. Copper and tin products are less efficacious for early blight in some areas. Last, applications of TPTH may result in injury to foliage of sensitive varieties, but injury is reduced and efficacy is improved when TPTH is combined with an EBDC fungicide.

Tomatoes. When used alone mancozeb and maneb are labeled to control anthracnose, early blight, gray leaf spot, late blight, leaf mold, and Septoria leaf spot fungal diseases. Mancozeb and maneb are also tank-mixed with copper fungicides to control bacterial spot and bacterial speck diseases. The principal alternatives for fungal disease control are chlorothalonil, strobilurins (azoxystrobin, trifloxystrobin), and Tanos (famoxadone + cymoxanil). The sole bacterial disease control alternative is Tanos, which only claims to suppress these diseases.

The alternatives Tanos and the strobilurins and are both considered high risks for pest resistance development and as such are labeled for a very limited number of applications and only in tank-mixtures and alternations with the available broad spectrum protectant fungicides (i.e., chlorothalonil and EBDCs). Chlorothalonil is not labeled for control of bacterial diseases and has a seasonal maximum rate that will sometimes preclude its use as a full-season EBDC fungicide replacement for control of fungal diseases.

The use of EBDCs in combination with copper are claimed to be very important in the principal tomato production states of California and Florida, where it is considered the only reliable control measure for bacterial spot and bacterial speck diseases. Furthermore, the EBDC treatment costs are about one-half that of the alternatives mentioned above.

5. Summary of Mitigation Measures

The following mitigation measures are necessary for mancozeb to be eligible for reregistration. These include use restrictions, voluntary cancellations and/or use deletions, and personal protective equipment (PPE).

1) Use Restrictions

Turf

All Formulations

- Establish a 3 day preharvest interval (PHI) on turf grown on sod farms

- For sod, restrict the amount that can be used to a maximum of 4 applications per year and reduce the maximum rate from 19 lbs ai/A to 17.4 lbs ai/A (69.6 lbs ai/A/season)
- Extend application interval from 7 to 10 days to 10 to 14 days

Wettable Powder (WP) Formulation

- Delete sod farm use from WP labels
- Use engineering controls (water soluble packs) for WP used on turf (golf courses & industrial parks)

Liquid Formulations

- Prohibit the application of liquids aerially to golf courses or sod farms, and prohibit the application of liquids in chemigation systems to golf courses

Papaya

- Reduce application rate from 4 to 2 lb ai/A

Cut Flowers/Greenhouse Grown Ornamentals

- Limit number of applications to 20 per year

Sweet Corn - prohibit homeowner use (remove from homeowner label); agricultural use remains

Human Flaggers - label must either prohibit human flaggers or require mechanical flaggers with aerial application

2) Personal Protective Equipment

WP Formulation, All Crops Except Turf

- Require single layer PPE, with PF 5 respirator and gloves (except pilots, groundboom applicators, and airblast applicators)
- Require single layer PPE for pilots, groundboom applicators, and airblast applicators

WP Formulation, Turf

- Delete sod farm use from WP labels
- Require use of engineering controls (water soluble packs) for WP used on turf (golf courses & industrial parks)

WP Formulation, Seed Treatment

- Require single layer PPE, with PF 5 respirator and gloves (all handlers except sewers and baggers)
- Require single layer PPE for sewers and baggers
- Require application as a liquid slurry or mist

DF (All Crops) and Liquid Formulations (All Crops Except Turf)

- Require single layer PPE with gloves for all handlers except aerial, airblast, & groundboom applicators
- Require single layer, no gloves, for aerial, airblast, & groundboom applicators (to avoid contaminating cab)

Liquid Formulations (Turf)

- Require single layer PPE with gloves and a PF 5 respirator for handlers mixing and loading to support chemigation application to sod
- Prohibit the application of liquids aerially to golf courses or sod farms, and prohibit the application of liquids in chemigation systems to golf courses

Seed Treatment, Liquids

- Require single layer PPE, with gloves (all handlers except sewers and baggers)
- Require single layer PPE for sewers and baggers

Potato Seed-Piece Treatment, Dust Formulation

- Require engineering controls, i.e., dust collection equipment, for commercial loaders and applicators
- Require single layer PPE with gloves and a PF5 respirator for all on-farm handlers

3) Use Cancellations and/or Deletions (ineligible for reregistration)

- foliar use on cotton
- pineapple propagation use
- residential lawn use
- pachysandra
- athletic fields

F. Other Labeling Requirements

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

1. Endangered Species Considerations

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers 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 analysis will consider regulatory changes recommended in this RED that are implemented at that time. 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 or the National Marine Fisheries Service as appropriate. If the Agency determines that the use of mancozeb "may affect" listed species or their designated critical habitat, EPA will

employ provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is complete, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposure to mancozeb at levels of concern.

2. 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, we will continue to work with all interested parties on this important issue.

From its assessment of mancozeb, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for mancozeb. Label statements implementing these measures are listed in the "spray drift management" section of the label table (Table 51) in Chapter V of this RED document. In the future, mancozeb product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

The Agency has determined that mancozeb is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section C below. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring label amendments, product specific data and additional generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data and label amendments that the Agency intends to require for mancozeb to be eligible for reregistration.

A. Manufacturing Use Products

1. Generic Data Requirements

The generic data base supporting the reregistration of mancozeb for the above eligible uses has been reviewed and determined to be substantially complete. However, there are a few outstanding generic data requirements for residue chemistry, aquatic toxicity, and environmental fate remaining, which are being addressed.

In addition, the Agency has identified data necessary to confirm the reregistration eligibility decision for mancozeb. These studies are listed below and will be included in the generic DCI for this RED, which the Agency intends to issue at a future date.

Toxicology:
870.6200 Acute neurotoxicity

Residue Chemistry:
860.1200 Directions for Use (potato, sugar beet, apple, field corn, wheat, barley, oats)
860.1340 Enforcement Analytical Method for Livestock Commodities

Occupational Exposure
875.1100 Dermal exposure monitoring, outdoor (potato seed piece treatment with liquids and dusts)
875.1300 Inhalation exposure monitoring, outdoor (potato seed piece treatment with liquids and dusts)

Environmental Toxicology
850.4100 Seed Germination and Seedling Emergence
850.1450 Vegetative Vigor
850.1735 Whole sediment acute toxicity for freshwater invertebrates
850.1740 Whole sediment acute toxicity for marine invertebrates

In addition, the Agency is requiring or reserving the guideline and nonguideline studies for ETU because the data on ETU are limited. These data are necessary to confirm the reregistration eligibility decision for mancozeb. These studies will be included in the generic DCI for this RED.

Toxicology
870.3700 Developmental toxicity study in rabbits
870.3800 2 Generation Reproductive Toxicity Study
870.6300 Developmental neurotoxicity study
Special study Comparative thyroid toxicity study in young and adult rats

Environmental Toxicology
850.1075 Acute Fish Toxicity Bluegill a freshwater fish dwelling in warm waters
850.1075 Acute Estuarine/Marine Toxicity Fish
850.1025 Acute Estuarine/Marine Toxicity Mollusk
850.1035 Acute Estuarine/Marine Toxicity Shrimp
850.1400 Early Life-Stage Fish for freshwater and estuarine/marine species (reserved)
850.1300 Life-Cycle Aquatic Invertebrate for freshwater and estuarine/marine species (reserved)
850.4400 Aquatic Plant Growth, Tiers I & II

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 51.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 51. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific 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.

C. Labeling Changes Summary Table

For mancozeb to be eligible for reregistration, all mancozeb labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 51 describes specific label amendments.

Table 51. Summary of Labeling Changes for Mancozeb

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into a fungicide for the following uses: [registrant fills in blank with only those uses being supported by MP registrants]." Technical and end-use product labels must be revised to delete all references to and use-directions for the following cancelled use patterns: foliar use on cotton, pineapple propagation use, all uses on turfgrass in residential settings and athletic fields, and all uses on pachysandra. Manufacturers of products formulated as wettable powders must prohibit the following: - application of wettable powder products to turf on sod farms - application of wettable powder formulations to turf unless packaged in water soluble packaging Manufacturers of products formulated as liquids must prohibit the following: - application of liquids by aerial or chemigation methods to golf courses - application of liquids aerially to sod farms. Manufacturers of products formulated as dusts must require closed systems for commercial seed-piece treatment.	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 manufacturing use product 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 manufacturing use product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use."	Directions for Use
Environmental Hazards Statements Required by	"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 Pollutant Discharge	Precautionary Statements

Description	Amended Labeling Language	Placement on Label
the RED and Agency Label Policies	Eliminations 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 Environmental Protection Agency."	
End-Use Products Intended for Occupational Use (WPS and non-WPS)		
PPE Requirements Established by the RED for Liquid Concentrate Formulations (For all uses except seed and seed piece treatment)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and socks, and - chemical-resistant gloves (except pilots, groundboom applicators, and airblast applicators)" "In addition, mixers/loaders supporting chemigation applications to turf on sod farms must wear 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." *Instruction to registrant: Drop the "N" type filter from the respirator statement if the pesticide product contains or is used with oil. "See engineering controls for additional requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED for Liquid Concentrate, Liquid Ready-To-Use, and Dry Flowable Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: - long-sleeved shirt,	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
(with directions for use as a seed treatment)	- long pants, - shoes and socks, and - chemical-resistant gloves (except handlers who are bagging the treated seed or sewing the bags)"	
PPE Requirements Established by the RED for Wettable Powder (WP) Formulations that are not packaged in water soluble packaging. (For all uses except seed and seed piece treatment)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixer, loaders, applicators, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and socks." "In addition, all handlers except pilots, groundboom applicators, and airblast applicators must wear: - 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." *Instruction to Registrant: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil. if the pesticide product contains, or is used with, oil. "See engineering controls for additional requirements"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct	Immediately following/below

Description	Amended Labeling Language	Placement on Label
for Wettable Powder (WP) Formulations that are not packaged in water soluble packaging. (For products with directions for use as a seed treatment)	material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixer, loaders, applicators, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and socks." "In addition, all handlers (except handlers who are bagging the treated seed or sewing the bags) must wear: - 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." "See engineering controls for additional requirements" *****Instruction to Registrant: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil. if the pesticide product contains, or is used with, oil.	Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED for Wettable Powder (WP) Formulations that <u>are</u> packaged in water soluble packaging.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixer, loaders, applicators, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and socks, and	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
	- chemical resistant gloves (except pilots, groundboom applicators, and airblast applicators)." "In addition, handlers performing tasks, such as spill clean-up, that involve contact with the dry wettable powder must wear: - 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." *Instruction to Registrant: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil. if the pesticide product contains, or is used with, oil. "See engineering controls for additional requirements"	
PPE Requirements Established by the RED for Dust Formulation and Wettable Powder Formulations (applied dry) (For products with directions for use as a seed-piece treatment)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Loaders, applicators, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and 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." *Instruction to Registrant: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil.	

Description	Amended Labeling Language	Placement on Label
	"See engineering controls for additional requirements."	
PPE Requirements Established by the RED for Dry Flowable (DF) Formulation	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and socks, and - chemical-resistant gloves (except pilots, groundboom applicators, and airblast applicators)" "See engineering controls for additional requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls: Closed System for Commercial Seed-Piece Treatment. Dust Formulations and Wettable Powder Formulations (applied dry)	"Loaders must use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people while it is being handled. The system must have a properly functioning dust control system and must be used and maintained in accordance with the manufacturer's written operating instructions. Handlers using the closed mixing/loading system must wear: - long-sleeved shirt, - long pants, - shoes and socks, and - chemical-resistant gloves (except pilots, groundboom applicators, and airblast applicators); and - must be provided with, have immediately available, and wear in an emergency, such as a broken package, spill, or equipment breakdown: 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."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
Engineering Controls: Wettable Powder Formulations packaged in water soluble packaging	"Engineering controls Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must: -- wear the personal protective equipment required in the PPE section of this labeling for mixers/loaders -- be provided, and have immediately available, and wear in an emergency, such as a broken package, spill, or equipment breakdown: 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."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls: Enclosed Cockpits for Aerial Applicators for products with directions for use permitting aerial application.	Enclosed Cockpits "Engineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls: Mechanical Flaggers or Global Positioning System (GPS) in lieu of Human Flaggers for products with directions for use permitting aerial application.	Mechanical Flagging Engineering Controls: "Engineering controls: Human flagging is prohibited. Flagging to support aerial application is limited to use of the Global Positioning System (GPS) or mechanical flaggers."	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. Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Amended Labeling Language	Placement on Label
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 (Must be placed in a box.)
Restricted-Entry Interval (for uses within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."	Directions for Use, under Agricultural Use Requirements box
Early Reentry Personal Protective Equipment for uses within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: - Coveralls, - Shoes and socks, and - Chemical-resistant gloves made of any waterproof material.	Directions for Use, Agricultural Use Requirements Box
General Application Restrictions All Formulations	"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 Directions for Use directly above the Agricultural Use Box
Application Restrictions Wettable Powder (WP) Formulation	End-use product labels must be revised to delete all references to and use directions for the following cancelled use pattern: Sod farm turf. End-use product labels must be revised to delete all references to and use directions for the following cancelled use pattern: turf (unless product is packaged in water soluble packaging)	Directions for Use
Application Restrictions Liquid (EC) Formulation	End-use product labels must be revised to delete all references to and use directions for the following cancelled use patterns: aerial application to sod farms, aerial application to golf courses, and chemigation application to golf courses.	

Description	Amended Labeling Language	Placement on Label
Application Restrictions (Risk Mitigation) All Formulations NOTE: The labels also must list the maximum application rates in pounds or gallons of formulation.	Sod Farm Turf: "Harvesting of treated turf is prohibited until 72 hours following application." - Limit to a maximum of 4 applications per year and a maximum rate of 17.4 lb ai/A per application. - Require a minimum of a 10 day interval between applications Golf Courses: - For cool season grasses; greens, tees and aprons - limit to a maximum of 5 applications per year at a maximum application rate of 17.4 lb ai/A per application - For cool season grasses; fairways - limit to a maximum of 4 applications per year at a maximum application rate of 17.4 lb ai/A per application - For warm season grasses; greens, tees and aprons - limit to a maximum of 4 applications per year at a maximum application rate of 17.4 lb ai/A per application - For warm season grasses; fairways - limit to a maximum of 3 applications per year at a maximum application rate of 17.4 lb ai/A per application - Require a minimum of a 10 day interval between applications All Other Turf: - Limit to a maximum of 4 applications per year and a maximum ~~one-time~~ application rate of 17.4 lb ai/A per application - Require a minimum of a 10 day interval between applications Papaya: The maximum application rate is 2 lb ai/A, and the maximum applications per year is 14. Cut Flowers and Cut Foliage: Limit to 20 applications per year. Restrict against homeowner application to sweet corn in the home garden. Technical and end-use product labels must be revised to delete all references to and use-directions for the following cancelled use patterns: foliar use on cotton, pineapple propagation use, all uses on turfgrass in residential settings and athletic fields, and all uses on pachysandra.	Directions for Use

Description	Amended Labeling Language	Placement on Label
Application Restrictions for seed treatment	"Mancozeb (trade name) fungicide must be applied to dry seed with conventional slurry or mist seed-treating equipment. For best results, the seed must be completely and uniformly covered with fungicide. For seed treatment, a dye must be added to (PRODUCT) which will impart an unnatural color to the seed"	Directions for Use
Application Restrictions for seed or seed-pieces that have been treated with this product that are then packaged or bagged for future use	"Seeds/seed-pieces that have been treated with this product that are then packaged or bagged for future use must contain the following labeling on the outside of the seed/seed-piece package or bag:" "When opening this bag or loading/pouring the treated seed/seed-pieces, 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." *Instructions: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil. "Treated Seed/Seed-Pieces - Do Not Use for Food, Feed, or Oil Purposes." "After the seeds/seed pieces have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours. Exception: Once the seeds/seed pieces 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 worker contact with the soil/media subsurface."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to aquatic organisms. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate."	Precautionary Statements: Hazards to Humans and Domestic Animals
Spray Drift Label Language for Products Applied as a Spray	**"SPRAY DRIFT MANAGEMENT"** "A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial, airblast, chemigation) can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product."	Spray Drift Label Language for Products Applied as a Spray

Description	Amended Labeling Language	Placement on Label
	Wind Speed "Do not apply at wind speeds greater than 15 mph. **Temperature Inversions** "If applying at wind speeds less than 3 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions." **Other State and Local Requirements** "Applicators must follow all state and local pesticide drift requirements regarding application of mancozeb. Where states have more stringent regulations, they must be observed." **Equipment** "All aerial and ground application equipment must be properly maintained and calibrated using appropriate carriers or surrogates." *Additional requirements for aerial applications:* 1. "The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter." 2. "Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety." 3. "When applications are made with a crosswind, the swath must be displaced downwind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind." *Additional requirements for ground boom application:* 1. "Do not apply with a nozzle height greater than 4 feet above the crop canopy."	

Appendix A

PLACEHOLDER FOR TABLE OF USE PATTERNS ELIGIBLE FOR REREGISTRATION

This is a placeholder for the table of mancozeb use patterns eligible for reregistration. This table will be released in January 2006.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 0005 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0005 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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

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

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

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

APPENDIX B1

Data Supporting FIFRA Guideline Requirements for the Reregistration of Mancozeb

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
PRODUCT CHEMISTRY				
830.1550	61-1	Chemical Identity & Composition	All	40381201, 45736501
830.1600 830.1620	61-2A	Starting Material & Manufacturing Process	All	40381201, 45736501, 40898301, 40391801, 40517502
830.1670	61-2B	Formation of Impurities	All	40381201, 45736501, 40373401, 40391801, 40517502
830.1700	62-1	Preliminary Analysis	All	40652201, 45750501, 41219401, 40678201
830.1750	62-2	Certification of limits	All	40381201, 40652201, 40678201
830.1800	62-3	Enforcement Analytical Method	All	40652201, 45736502, 40517501, 40678201, 41357901
830.6302	63-2	Color	All	40381202, 45736503, 40391801, 40517502
830.6303	63-3	Physical State	All	40381202, 45736503, 40391801, 40517502
830.6304	63-4	Odor	All	40381202, 45736503, 40391801, 40517502
830.7050		UV/Visible Absorption	All	45736503
830.7100		Viscosity	All	Not Applicable
830.7200	63-5	Melting Point	All	40391801, 40517502, 40381202, 45736503
830.7220	63-6	Boiling Point	All	Not Applicable
830.7300	63-7	Density	All	40381202, 45736503, 40391801, 40517502
830.7840 830.7860	63-8	Solubility	All	40381202, 45736503, 40898302, 40391801, 40517502, 41357901

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
830.7950	63-9	Vapor Pressure	All	40381202, 45736503, 40391801, 40517502
830.7370	63-10	Dissociation Constant	All	40381202, 45736503, 40391801, 40517502
830.7550	63-11	Octanol/Water Partition Coefficient	All	40381202, 45736503, 40391801, 40517502
830.7000	63-12	pH	All	40381202, 45736503, 40391801, 40517502
830.6313	63-13	Stability	All	41357901, 41056601, 45736503
	63-14	Oxidizing/Reducing Action	All	45736503
	63-15	Flammability	All	Not Applicable
	63-16	Explodability	All	45736503
	63-17	Storage Stability	All	45736503
	63-19	Miscibility	All	45736503
	63-20	Corrosion Characteristics	All	45736503
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity - Quail	ABCK	Data Gap for TGAI* 00080716 (supplemental)
850.2200	71-2A	Avian Dietary Toxicity - Quail	ABCK	Waived
850.2200	71-2B	Avian Dietary Toxicity - Duck	ABCK	Waived
850.2300	71-4A	Avian Reproduction - Quail	ABCK	44159501, 44238001
850.2300	71-4B	Avian Reproduction - Duck	ABCK	41948401
850.1075	72-1A	Fish Toxicity Bluegill	ABCK	Data Gap for TGAI*, Reserved for TEP 40118501, 00097173, 000097147, 45934702 (all supplemental)

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
850.1075	72-1B	Fish Toxicity Sheepshead Minnow	ABCK	Reserved
850.1075	72-1C	Fish Toxicity Rainbow Trout	ABCK	40118502, 44950503, 45910401 for TGAI Reserved for TEP
850.1010	72-2A	Acute Aquatic Invertebrate Toxicity	ABCK	40118503, 40467503, 45910402, 44950502
None	72-3A	Estuarine/Marine Toxicity - Fish	ABCK	Reserved for TEP 40586802, 40586804, 41844901, 41844902 (all supplemetal)
None	72-3B	Estuarine/Marine Toxicity - Mollusk	ABCK	40885102
None	72-3C	Estuarine/Marine Toxicity - Shrimp	ABCK	41822901, 41822902
850.1400	72-4A	Fish Early Life Stage	ABCK	43230701
	72-4B	Life Cycle Aquatic Invertebrate	ABCK	40953802
850.4100	123-1(a)	Seedling Germination/Seedling Emergence	ABCK	44283401
850.4150	123-1(b)	Vegetative Vigor	ABCK	44283401
850.4400	122-2	Aquatic Plant Growth, Tier I	ABCK	Data Gap*
	123-2	Aquatic Plant Growth, Tier II	ABCK	43664701, 44283402
850.3020	141-1	Honey Bee, acute contact	ABCK	9181, 44950504
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	All	00142522
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	All	00142522

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
870.2400	81-4	Primary Eye Irritation-Rabbit	All	00142522
870.2500	81-5	Primary Skin Irritation	All	00142522
870.2600	81-6	Dermal Sensitization	All	40469501
870.3100	82-1A	90-Day Feeding - Rodent	All	00160704, 00154192
870.3150	82-1B	90-Day Feeding - Non-rodent (Dog)	All	00160705
870.3465	82-4	90-Day Inhalation - Rodent	All	00159471
870.3200	82-2	21-Day Dermal - Rabbit/Rat	All	40588201
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	All	41903601
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	All	41810501
870.4200	83-2A	Oncogenicity - Rat	All	41903601
870.4200	83-2B	Oncogenicity - Mouse	All	41981801
870.3700	83-3A	Developmental Toxicity - Rat	All	93929
870.3700	83-3B	Developmental Toxicity - Rabbit	All	40433001
870.3800	83-4	2-Generation Reproduction - Rat	All	41365201
870.5140	84-2A	Gene Mutation (Ames Test)	All	148233, 148234
870.5375	84-2B	Structural Chromosomal Aberration	All	148327, 148329, 149193, 148239, 40810202
None	84-4	Other Genotoxic Effects	All	148328, 148239, 40611701, 40810205, 40810201
870.7485	85-1	General Metabolism - Rat	All	159611, 159612
870.7485	85-1	General Metabolism - Mouse	All	41656301

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
870.600	81-8	Acute Neurotoxicity Screening Battery	All	Data gap - new data requirement
870.6200	82-7	Subchronic Neurotoxicity Screening Battery	All	42034101
870.7600	85-3	Dermal Absorption in Rats	All	40955401, 00127947, 00127950 (combined)
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	ABC	Mancozeb: 44959601, 41836901, 41133901, 44961701, 44959602, 41836902, 44959603, 42560201 ETU: 44959601, 41836901, 41133901, 44961701, 44959602, 41836902, 42560201, 44959603
875.2200	132-1B	Soil Residue Dissipation	ABC	Waived
875.2400	133-3	Dermal Passive Dosimetry Exposure	ABCD	PHED v 1.1, ORETF OMA002
875.2500	133-4	Inhalation Passive Dosimetry Exposure	ABCD	PHED v 1.1
None	231	Estimation of Dermal Exposure at Outdoor Sites	ABCD	PHED v 1.1, ORETF OMA002
None	232	Estimation of Inhalation Exposure at Outdoor Sites	ABCD	PHED v 1.1
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	All	0097162, 40258201 (combined)
835.2240	161-2	Photodegradation - Water	ABC	00162103
835.2410	161-3	Photodegradation - Soil	ABC	00162104

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
835.4100	162-1	Aerobic Soil Metabolism	ABC	45744501 (supplemental), Reserved
835.4200	162-2	Anaerobic Soil Metabolism	ABC	Reserved
835.4400	162-3	Anaerobic Aquatic Metabolism	ABC	Reserved 40258203, 00088820 (combined)
835.4300	162-4	Aerobic Aquatic Metabolism	ABC	46204301
835.1240	163-1	Leaching/Adsorption/Desorption	ABCK	40588302, 40222901, 00088822 (combined)
835.6100	164-1	Terrestrial Field Dissipation	ABCK	40923601, 44524101 (combined)
None	165-4	Bioaccumulation in Fish	ABCK	Waived
RESIDUE CHEMISTRY				
860.1200		Directions for Use	All	Required for potato, sugar beet, apple, field corn, wheat, barley, oats
860.1300	171-4A	Nature of Residue - Plants	ABD	00064927, 00064932, 00088826, 00088829, 00088833, 00088894, 00088921, 00088923, 00088924, 00097110, 00097112, 00152696, 00156715, 00160703, 00164509, 00164510, 41095201, 42840501
860.1300	171-4B	Nature of Residue - Livestock	ABD	00064930, 00064931, 00064932, 00088831, 00088834, 00088835, 00088924, 00097148, 00160780, 00160781, 00164879, 00164880, 42840501, Data Gap for ruminant feeding study*
860.1340	171-4C	Residue Analytical Method - Plants	ABD	00040149, 00040151, 00088891, 00090132, 00097112, 00098667, 41343101

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
860.1340	171-4D	Residue Analytical Method - Animals	ABD	00088891, 00088892, 00089871, 00097112, 0097861, 00129291, 41343101, required for ruminants*
860.1360		Multiresidue Methods	ABD	40764601
860.1380	171-4E	Storage Stability Data - Plants	ABD	41070001, 41643601, 41976101, 42139901, 43357201, 44038801, 44101101, 44629501, 44629502, 44725101, 44730801
860.1380	171-4E	Storage Stability Data - Animals	ABD	41643601, 42556001
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	ABD	00089871, 00097862, 00155843, 0155844, 00129291
Crop Field Trials - Root and Tuber Vegetables Group				
860.1500	171-4K	Sugar beet	ABD	00089875, 00091501, 00097137, 00159477, 00160726, 40869712, 44725101
860.1500	171-4K	Carrot	ABD	00160707, 43436801, 44023001, 44725601
860.1500	171-4K	Ginseng	ABD	44728301
860.1500	171-4K	Potato	ABD	00071616, 00097024, 00097110, 00097113, 00097123, 00097151, 00097183, 00159480, 00160708, 40121002, 40121003, 40913301, 43336101, 43336102, 44167901
Crop Field Trials - Leaves of Root and Tuber Vegetables Group				
860.1500	171-4K	Sugar beet tops	ABD	00089875, 00091501, 00159477, 00160726, 40869712, 44725101

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
Crop Field Trials - Bulb Vegetables Group				
860.1500	171-4K	Onion	ABD	00097023, 00160723, 40869708, 41092003, 43294301 , 43338701, 43336103, 44725501
Crop Field Trials - Leafy Vegetables (Except *Brassica*) Crop Group				
860.1500	171-4K	Celery	ABD	00097109, 00157431, 00157432, 00160718, 43436701, additional celery field trials are required for FIFRA section 3 registration**
860.1500	171-4K	Fennel	ABD	translated from celery
Crop Field Trials - Fruiting Vegetables (Except Cucurbits) Group				
860.1500	171-4K	Tomato	ABD	00089874, 00088926, 00097105, 00097119, 00160709, 40869713, 40869714, 41844801, 41901102, 43140402, 44051501
Crop Field Trials - Cucurbit Vegetables Group				
860.1500	171-4K	Cucumber	ABD	00097109, 00160710, 40869707, 41092006, 44074301
860.1500	171-4K	Melon	ABD	00097109, 00160711, 44074302
860.1500	171-4K	Summer Squash	ABD	00097109, 00160712, 44023101

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
Crop Field Trials - Pome Fruits Group				
860.1500	171-4K	Apple	ABD	00097109, 40128802, 41092007, 41731801, 41831501, 42036901, 43357201
860.1500	171-4K	Crabapple	ABD	translated from apple
860.1500	171-4K	Pear	ABD	00091500, 40128801, 40913305, 40913306, 44725901
860.1500	171-4K	Quince	ABD	translated from pear
Crop Field Trials - Cereal Grains Group				
860.1500	171-4K	Barley grain	ABD	00091503, 00093261, 00160717
860.1500	171-4K	Corn grain & aspirated grain fractions	ABD	00097109, 00131898, 00160719, 40869705, 44080701
860.1500	171-4K	Popcorn grain	ABD	translated from sweet corn
860.1500	171-4K	Sweet Corn, Kernals plus cobs with husks removed (K + CWHR)	ABD	00097109, 00160720, 41093201, 42155901, 44154601
860.1500	171-4K	Oat grain	ABD	translated from wheat grain
860.1500	171-4K	Rye Grain	ABD	translated from wheat grain
860.1500	171-4K	Wheat Grain and aspirated fractions	ABD	40869716, 41092005, 44802501, 00091503, 00160714, 40869715
Crop Field Trials - Forage, Fodder, and Straw of Cereal Grains Group				
860.1500	171-4K	Barley hay and straw	ABD	00093261, 00159473, 00160717
860.1500	171-4K	Field Corn forage and stover	ABD	00093263, 00097109, 00131898, 00160719, 40869705, 44080701

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
860.1500	171-4K	Popcorn stover	ABD	translated from sweet corn stover
860.1500	171-4K	Sweet Corn Forage and stover	ABD	00093263, 44154601
860.1500	171-4K	Oat Forage, hay, and straw	ABD	translated from wheat forage and straw
860.1500	171-4K	Rye forage and straw	ABD	translated from wheat forage and straw
860.1500	171-4K	Wheat forage, hay, and straw	ABD	00091503, 00160714, 40869715, 40869716, 41092005, 44802501
Crop Field Trials - Miscellaneous Commodities				
860.1500	171-4K	Asparagus	ABD	00097021, 00160715, 40869701, 40869702, 44747501
860.1500	171-4K	Banana	ABD	00090132, 00160716, 40913303, 40913304, 44726001
860.1500	171-4K	Cotton seed and gin byproducts	ABD	00093259, 44038801
860.1500	171-4K	Cranberry	ABD	00093258, 00160721, 40869706, 44725701
860.1500	171-4K	Grape	ABD	00089873, 00093258, 00160722, 41092001, 41092002, 44730801
860.1500	171-4K	Papaya	ABD	00089879, 00090776, 00160724, 40869709, 40869710
860.1500	171-4K	Peanut nutmeat and hay	ABD	00093260, 00097167, 00160725, 40869711, 41092004, 41844802
860.1500	171-4K	Sugar apple	ABD	44729901
860.1500	171-4K	Tobacco	ABD	Data Gap*
Crop Field Trials - Seed Treatment				

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
860.1500	171-4K	Flax	ABD	41091801
860.1500	171-4K	Rice	ABD	40869717, 41091801
860.1500	171-4K	Safflower	ABD	Data Gap*
860.1500	171-4K	Sorghum	ABD	40869717, 41091801
Processing Studies - Processed Food/Feed				
860.1520		Apple	ABD	0159472, 0159478, 40128802, 44101101
860.1520		Barley	ABD	00159473; Data Gap (pearled barley)*
860.1520		Field Corn	ABD	00159474, 41091701, 44134201
860.1520		Sweet Corn	ABD	41093201
860.1520		Grape	ABD	00093258, 00159475, 00159479, 41483801
860.1520		Oats	ABD	Data Gap (rolled oats)*
860.1520		Peanut	ABD	40869711
860.1520		Potato	ABD	00159480, 41091601, Data Gap*
860.1520		Sugar Beet	ABD	00159477
860.1520		Tomato	ABD	00159481, 40768001
860.1520		Wheat	ABD	00160714, 00091503, Data Gap for middlings & germ*
Processing Studies - Meat, Milk, Poultry, Eggs				
860.1480		Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	ABD	00089871, 00097862, 00155843
860.1480		Milk	ABD	0155843

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
860.1480		Eggs and Poultry Fat, Meat, and Meat Byproducts	ABD	00089871, 00129291, 00155844
860.1560		**Reduction of Residues**	ABD	00097110, 00159476, 00160708, 00160709, 44064001, 44167901
860.1850	**165-1**	**Confined Rotational Crop**	ABD	Data Gap*

* These studies were required under a previous DCI, GDCI-014504-16148, which was issued in April 1987. Data remain outstanding.

** Data requirement for a registration action. Because this study is not related to this RED decision, it is not included in the generic DCI for this RED.

APPENDIX B2

Data Supporting FIFRA Guideline Requirements for the EBDC Metabolite/Degradate ETU

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
	ECOLOGICAL EFFECTS			
850.1010	72-2A	Acute Aquatic Invertebrate Toxicity - *Daphnia magna*	All	405910402, 46020901
850.1075	72-1	Acute Toxicity - Estuarine/Marine Fish	All	New Data Requirement (Confirmatory)
850.1025	72-3B	Acute Toxicity - Estuarine/Marine Mollusk	All	New Data Requirement (Confirmatory)
	72-3C	Acute Toxicity - Estuarine/Marine Shrimp	All	New Data Requirement (Confirmatory)
850.1075	72-1A	Acute Fish Toxicity - Bluegill	All	New Data Requirement (Confirmatory)
850.1075	72-1C	Fish Toxicity Rainbow - Trout	All	45910401, 46020903
850.1300	72-4B	Life Cycle Aquatic Invertebrate for freshwater and estuarine/marine	All	Reserved - Potential New Data Requirement
850.1400	72-4	Fish Early Life Stage for freshwater and estuarine/marine	All	Reserved - Potential New Data Requirement
850.4400	122-2	Aquatic Plant Growth, Tier I	All	Data Gap*
	123-2	Aquatic Plant Growth, Tier II	All	45910403, 46020902 (supplemental), Data Gap*

Guideline Requirement			Use Pattern	MRID Citation
Guideline Number		Study Title		
New	Old			
TOXICOLOGY				
870.3700	83-3	Developmental Toxicity Study in Rabbits	All	New Data Requirement (Confirmatory)
870.3800	83-4	2 Generation Reproductive Toxicity Study	All	New Data Requirement (Confirmatory)
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	All	NTP Bioassay
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	All	42338101, 42338102
870.6300	None	Developmental Neurotoxicity Study	All	New Data Requirement (Confirmatory)
None	None	Comparative Thyroid Toxicity Study in Young and Adult Rats	All	New Data Requirement (Confirmatory)
ENVIRONMENTAL FATE				
835.2120	161-1-SS	Hydrolysis	All	40466103
835.2240	161-2-SS	Photodegradation - Water	All	40466102
835.2410	161-3-SS	Photodegradation - Soil	All	40466101
835.4100	162-1-SS	Aerobic Soil Metabolism	All	40838701, 45156401, 45225101 (all supplemental)†
835.4400	162-3-SS	Anaerobic Aquatic Metabolism	All	00163335†
835.1240	163-1-SS	Leaching/Adsorption/Desorption	All	40588301 (supplemental)
835.6100	164-1-SS	Terrestrial Field Dissipation	All	00088923 (supplemental)
None	165-4-SS	Bioaccumulation in Fish	All	Waived

* These studies were required under a previous DCI, GDCI-014504-16148, which was issued in April 1987. Data remain outstanding.

† Registrants must completely characterize bound species to fulfill these guideline requirements.

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, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The preliminary risk assessments for mancozeb are available in the public docket and in e-dockets under docket number OPP-2004-0078. This contains risk assessments and related documents as of November 2004. During the comment period, the registrant submitted additional data for mancozeb and ETU. EPA reviewed these data and incorporated them into the revised risk assessments for mancozeb. These revised risk assessments form the basis of the regulatory decision described in this RED. These risk assessment and related documents are available under docket number OPP-2005-0176. In addition, the Agency's decision regarding whether mancozeb and related pesticides share a common mechanism of toxicity may be found on the internet at http://www.epa.gov/oppsrrd1/cumulative/dithiocarb.pdf.

Technical support documents for the Mancozeb RED include the following Human Health Risk Assessment Documents:

1. *Mancozeb. Health Effects Division (HED) Human Health Risk Assessment to Support Reregistration,*" dated June 3, 2005;
2. *ETU from EBDCs: Health Effects Division (HED) Human Health Risk Assessment of the Common Metabolite/Degradate ETU to Support Reregistration*," dated June 8, 2005;
3. *Mancozeb, Maneb, and Metiram: Revised Aggregate Dietary Assessment of the Common Metabolite/Degradate Ethylene Thiourea (ETU) to Support the Reregistration including the Aggregate ETU Drinking Water Assessment,* dated May 26, 2005;
4. *Revised Acute Probabilistic, Chronic, and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision,* dated June 2, 2005.
5. *Mancozeb. Residue Chemistry Chapter of the Reregistration Eligibility Decision,* dated June 14, 2005;
6. *Mancozeb: 2nd Revised Occupational and Residential Exposure Assessment and recommendations for the Reregistration Eligibility Decision Document,* " dated May 31, 2005;
7. *Mancozeb Toxicity Endpoints for Risk Assessment,* dated June 3, 2005;

8. *Mancozeb. Short-Term Aggregate Postapplication Risk in Home Gardens to Mancozeb-derived ETU*, dated September 20, 2005;
9. *The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity,* dated December 19, 2001 (located at http://www.epa.gov/oppsrrd1/cumulative/dithiocarb.pdf);
10. *Mancozeb HED Toxicology Chapter for the Reregistration Eligibility Decision Document (RED)*, dated March 6, 2000;
11. *ETU-3rd Report of the Hazard Identification Assessment Review Committee,* dated May 28, 2003;

The following Environmental Fate and Effects Documents:

1. *Environmental Fate and Ecological Risk Assessment for Mancozeb, Section 4 Reregistration for Control of Fungal Diseases on Numerous Crops, a Forestry Use on Douglas Firs, Ornamental Plantings, and Turf (Phase 3 Response),* dated June 22, 2005;
2. *Environmental Fate and Ecological Risk Assessment for Ethylenethioureas (ETU) a Common Degradate of the Ethylenebisdithio-carbamate fungicides (EBDCs): Metiram, Mancozeb, and Maneb...(Phase 3 Response),* dated June 21, 2005

And the following documents on use and usage, and biological and economic analysis:

1. *BEAD Deliverables for the EBDC RED,* dated May 23, 2005; and
2. *Usage Report in Support of the Mancozeb Reregistration*, dated March 24, 2005.

Appendix D

MRID	Citation Reference
9181	Atkins, E.L., Jr.; Anderson, L.D.; Greywood, E.A. (1969) Effect of Pesticides on Apiculture: Project No. 1499. (Unpublished study received Jul 29, 1976 under 352-342; prepared by Univ. of California Riverside, Dept. of Entomology, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:224800-C)
40149	Gordon, et al. (1967) *Journal of the Association of Official Analytical Chemists* 50(5):1103-1108. (Incomplete article dealing with Ethylenebisdithiocarbamate residues; also in unpublished submission received Apr 3, 1972 under 2F1258; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 095544-C)
40151	Rohm & Haas Company (1960) Determination of Micro Quantities of Dithanes in Plants, Fruits, and Vegetables. Method 852-2 dated Apr 25, 1960. (Unpublished study received Apr 3, 1972 under 2F1258; CDL:095544-E)
64927	Rohm and Haas Company (1970) Components of Residues from Dithane M-45 in and on Leafy Plants: RAR Memorandum No. 571. (Unpublished study received Aug 2, 1972 under 1F1050; CDL:091882-C)
64930	Rohm and Haas Company (1970) The Fate of ^{14}C-Ethylene thiourea Ingested by Dairy Cows: An Experiment to Determine the Occurrence of Residues and Metabolites in Milk, Tissues, and Excreta: Research Report No. 23-22. (Unpublished study received Aug 2, 1972 under 1F1050; CDL:091882-F)
64931	Margolin, S. (1970) Feeding of ^{14}C-Labeled Ethylene thiourea to Dairy Cattle to Obtain Samples of Milk, Tissues, and Excreta for Residue Analysis: Contract No. 32-338-12-69. (Unpublished study received Aug 2, 1972 under 1F1050; prepared by Affiliated Medical Enterprises, Inc., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:091882-G)
64932	Rohm and Haas Company (1970) Isolation of ^{14}C Activity in Naturally Occurring Material from Substrates Treated with ^{14}C- Dithane M-45: RAR Memorandum No. 576. (Unpublished study received Aug 2, 1972 under 1F1050; CDL:091882-H)
71616	Ciba-Geigy Corporation (1981) Study of Various Compounds for Residue Tolerances in Potatoes: AG-A 4601. (Compilation; unpublished study, including AG-A 4614, 4615, 4903..., rcvd Apr 15, 1981 under 100-607; CDL:070020-A)
80716	Harper, K.H.; Palmer, A.K. (1964) Toxicity of Dithane M 45 to the Mallard Duck: 1000/64/215:2. (Unpublished study received Nov 9, 1965 under 6F0467; prepared by Huntingdon Research Centre, Eng- land, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 090519-B)

MRID	Citation Reference
88820	Swan, L.H. (1978) Degradation of Dithane M-45 (Mancozeb) and Ethylenethiourea under Anaerobic Aquatic Conditions: TR 34F- 78-6. Includes method 1853-1 dated Jul 19, 1973. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-A)
88822	Rohm and Haas Company (19??) Soil Adsorption Studies with ^{14}C Dithane M-45: Tech. Rept. #23-71-20. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070528-D)
88826	Nash, R.G. (1976) Uptake of ethylenebis(dithiocarbamate) fungicides and ethylenethiourea by soybeans. *Journal of Agricultural and Food Chemistry* 24(3):596-601. (Also In unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-H)
88829	Hoagland, R.E.; Frear, D.S. (1976) Behavior and fate of ethyl- enethiourea in plants. *Journal of Agricultural and Food Chemistry* 24(1):129-131. (Incomplete; also In unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-L)
88831	Rohm and Haas Company (1969) A Study To Determine Residue Levels in Milk and Tissues from a Cow Fed ^{14}C-Dithane M-45: Lab 23 Res. Rpt. No. 18. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070528-N)
88833	Lyman, W.R.; Lacoste, R.J. (1975) New developments in the chemistry and fate of ethylenebisdithiocarbamate fungicides. Pages 67- 74 in *Environmental Quality and Safety: Supplement Volume III: Pesticides: Lectures held at the IUPAC Third International Congress of Pesticide Chemistry; Jul 3-9, 1974; Helsinki, Finland.* Edited by Frederick Coulston; et al. Stuttgart, West Germany: Georg Thieme Publishers. (Also in unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-P)
88834	Saxton, A.D. (1972) A [C14]-ethylene Thiourea Rat-feeding Study: An Experiment To Determine the Excretion Pattern and the Ac- cumulation and Decline in Thyroid Tissues of [C14]- Residues: Research Report No. 23-51. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-Q)
88835	Saxton, A.D. (1972) A [C14]-Jaffe's Base Rat-feeding Study: An Experiment To Determine the Excretion Pattern and the Accumulation of [C14]- Residues in the Body Tissues: Research Report No. 23-54. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 070528-R)

MRID	Citation Reference
88891	Haines, L.D.; Adler, I.L. (1973) Gas chromatographic determination of ethylene thiourea residues. *Journal of the Association of Official Analytical Chemists* 56(2):333-337. (Also in unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070519-F)
88892	Rohm and Haas Company (1970) The Determination of Ethylene Thiourea in Milk as the Diacetyl Derivative: RAR Memorandum No. 574. Method dated Jul 2, 1970. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070519-G)
88894	Lyman, W.R. (1977) The Fate of Ethylenebisdithiocarbamate Fungicides in the Environment. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070520-A)
88921	Graham, W.H.; Bornak, W.E. (1972) Greenhouse Studies with [C14]- Ethylene Thiourea on Potatoes and Tomatoes and Photodecomposition in Water: Laboratory 23 Research Report No. 23-52. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070525-G)
88923	Rhodes, R.C. (1977) Studies with manganese [^{14}C]ethylenebis(dithiocarbamate) ([^{14}C]maneb) fungicide and [^{14}C]ethylenethiourea ([^{14}C]ETU) in plants, soil, and water. *Journal of Agricultural and Food Chemistry* 25(3):528-533. (Also In unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070525-I)
88926	Rohm and Haas Company (1973) ETU Residues in Tomatoes Treated with ETU and Potential ETU Precursors: TR 23-73-2. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070526-A)
88927	Adler, I.L. (1973) Ethylenethiourea Levels in Dithane M-45 Spray Slurries and Spray Deposits: TR 23-73-20. (Unpublished study, including letter dated Jun 28, 1973 from I.L. Adler to W.R. Lyman, received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070527-A)
89871	Rohm & Haas Company (1962) Microdetermination of Dithanes in Milk, Eggs and Animal Tissue. (Compilation; unpublished study received Nov 15, 1962 under PP0382; CDL:090412-C)
89873	Rohm & Haas Company (1962) Analytical Results and Residue Analysis of Dithane M-45 on Grapes. (Compilation; unpublished study received Nov 15, 1962 under PP0382; CDL:090412-E)
89874	Rohm & Haas Company (1962) Dithane M-45 Residue Analysis: Tomatoes. (Compilation; unpublished study received Nov 15, 1962 under PP0382; CDL:090412-F)

MRID	Citation Reference
89875	Rohm & Haas Company (1962) Dithane M-45 Residue Analysis: Sugar Beets. (Compilation; unpublished study received Nov 15, 1962 under PP0382; CDL:090412-G)
89879	Isenhour, L.L. (1962) Dithane M-45 Residue Analysis: Papaya. (Unpublished study received Nov 15, 1962 under PP0382; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:090412-K)
90132	Rohm & Haas Company (1962) Residues of Dithane M-45 on Bananas|. Includes method dated Apr 12, 1962 and method 852-2 dated Aug 2, 1955. (Compilation; unpublished study, including letter dated May 8, 1961 from R.T Schuckert to Dr. Swisher, Mr. Kampmeier, Dr. Levesque, et al., received Aug 1, 1962 under PP0374; CDL: 090403-C)
90776	Rohm & Haas Company (1964) Residue Analysis and Analytical Method (Additional Data). (Compilation; unpublished study received Jan 2, 1964 under PP0422; CDL:090459-A)
91500	Rohm & Haas Company (1966) Residue Summary: Dithane. (Compilation; unpublished study received Feb 28, 1966 under 6F0467; CDL:090518-A)
91501	Rohm & Haas Company (1964) Residue Summary: Dithane. (Compilation; unpublished study received Feb 28, 1966 under 6F0467; CDL:090518-E)
91503	Rohm & Haas Company (1965) Residue Summary: Dithane. (Compilation; unpublished study received Feb 28, 1966 under 6F0467; CDL:090518-G)
93258	Rohm & Haas Company (1965) Analytical Results of Dithane M-45 Residues. (Compilation; unpublished study received Nov 2, 1965 under 6F0476; CDL:090532-E)
93259	Rohm & Haas Company (1964) Analytical Results of Dithane M-45 Residues: Cotton Seed. (Compilation; unpublished study received Nov 2, 1965 under 6F0476; CDL:090532-F)
93260	Rohm & Haas Company (1965) Analytical Results of Dithane Residues in Peanuts, Peanut Hay and Grain Millings. (Compilation; un- published study received on unknown date under 6F0476; CDL: 090532-G)
93261	Rohm & Haas Company (1965) Analyses for Residues of Dithane in Grain and Straw. (Compilation; unpublished study received on unknown date under 6F0476; CDL:090532-H)

MRID	Citation Reference
93929	Kam, C.; Stevens, K.R.; Gallo, M.A. (1980) Teratologic Evaluation of Dithane M-45 in the Albino Rat: Volume I: Snell Project # 10065-009. (Unpublished study, including letter dated Dec 4, 1979 from W.T. Lynch to Kent Stevens, received Jan 28, 1982 under 707-78; prepared by Foster D. Snell Div., Booz, Allen & Hamilton, Inc., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:246663-A)
97021	Rohm & Haas Company (1966) Residue Summary: Dithane RH-539. (Compilation; unpublished study received Nov 1, 1966 under 7F0625; CDL:090817-I)
97023	Rohm & Haas Company (1967) Residue Summary: Dithane M-45|. (Compilation; unpublished study received on unknown date under 7F0625; CDL:090817-K)
97024	Rohm & Haas Company (1967) Residue Summary: Dithane M-45. (Compilation; unpublished study received on unknown date under 7F0625; CDL:090817-L)
97105	Wagner, F.E., Jr. (1966) Letter sent to C.F. Gordon dated Jul 18, 1966: Analytical results of pesticide residues. (Unpublished study received Nov 7, 1966 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:024199-B)
97109	Rohm & Haas Company (1969) Results of Tests on the Amount of Residue Remaining in Crops Including a Description of the Analytical Method: Dithane M-45. (Compilation; unpublished study received Sep 24, 1972 under 2F1258; CDL:091789-B)
97110	Rohm and Haas Company (1970) A Study To Determine Residue Levels in Milk, Tissues and Excreta from Cows Fed Fieldaged Residues Due to Dithane M-45 on Alfalfa Hay: Research Report No. 23-21. (Unpublished study received Aug 1, 1971 under 1F1050; CDL: 091880-B)
97112	Rohm & Haas Company (1970) Results of Tests on the Amount of Res- idue Remaining in Potatoes, Animal Tissues, Milk and Soil Including a Description of the Analytical Methods Used: Dithane M-45. (Compilation; unpublished study received Aug 2, 1971 under 1F1050; CDL:091881-A)
97113	Rohm & Haas Company (1971) Dithane M-45 Residues in Potatoes|. (Compilation; unpublished study received Aug 3, 1972 under 1F1050; CDL:091883-A)
97119	Rohm & Haas Company (1964) Residue Analysis and Analytical Method. (Compilation; unpublished study received Nov 9, 1965 under 6F0467; CDL:092756-C)
97123	Rohm & Haas Company (1968) Residue Studies of Dithane M-45 on Potatoes. (Compilation; unpublished study, including RAR memo no. 121, received Jan 23, 1969; Mar 26, 1968 under 8F0625; CDL:092919-B)

MRID	Citation Reference
97137	Rohm & Haas Company (1963) Residues of Dithane M-45 in Sugar Beets. (Compilation; unpublished study received Apr 9, 1964 under 707-78; CDL:101461-A)
97147	McCann, J.A. (1967) Ditahane M-45: Bluegill (*Lepomis macrohirus*): Test Nos. 58 & 55. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:108279-A)
97148	Rohm and Haas Company (19??) Status of Research on Dithane M-45 Residues. (Unpublished study received Oct 11, 1968 under 707- 78; CDL:119708-A)
97151	Rohm & Haas Company (1962) Analytical Results on Dithane Residue: Potatoes. (Unpublished study received May 4, 1962 under un- known admin. no.; CDL:119727-A)
97162	Haines, L.D. (1973) The Hydrolytic Decomposition of Dithane M-45 at Room Temperature: Technical Report No. 3923-73-25. (Unpubished study received Jan 3, 1974 under 707-78; submitted by Rohm and Haas Co., Philadelphia, Pa.; CDL:120481-K)
97167	E.I. du Pont de Nemours & Company, Incorporated (1971) Data Supporting the Use of Benlate® Benomyl Fungicide plus Manzate® 200 Fungicide (Tank Mix) for Control of Certain Diseases of Peanuts. (Unpublished study received on unknown date under 352-341; CDL:126318-A)
97173	McCann, J.A.; Pitcher, F. (1973) Dithane M-45: Bluegill (*Lepomis macrochirus*): Test No. 544. (U.S. Environmental Protection Agency, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:128295-A)
97183	Rohm and Haas Company (1978) Analytical Report of Pesticide Residues via CSI2^ Method. (Unpublished study received Apr 23, 1979 under 707-78; CDL:238645-A)
97861	Rohm and Haas Company (1970) The Determination of Ethylene Thiourea in Cow Tissues and Fat as the Diacetyl Derivative: RAR Memorandum No. 590. Method dated Jul 23, 1970. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070519-H)
97862	Lyman, W.R. (1981) Residues in Milk and Meat from Cows Fed Alfalfa Hay Having Residues from Dithane M-45: Technical Report No. 36F- 81-21. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm and Haas Co., Philadelphia, Pa.; CDL:070519-J)
98667	Interregional Research Project Number 4 (1973) Dithane M-45--Taro Project. (Compilation; unpublished study received on unknown date under 4E1508; CDL:094008-B; 094007)

MRID	Citation Reference
127947	Burke, S. (1983) Suitability of the Dithane M-45 Percutaneous Absorption Study in Rats to Fulfill the Mancozeb Data Call-in Requirement. (Unpublished study received Apr 28, 1983 under 707-78; submitted by Rohm & Haas Co., Philadelphia, PA; CDL: 250063-A)
127950	Haines, L. (1980) Dithane M-45 Percutaneous Absorption in Rats: Technical Report No. 34F-80-9. (Unpublished study received Apr 28, 1983 under 707-78; submitted by Rohm & Haas Co., Philadelphia, PA; CDL:250063-D)
129291	Rohm & Haas Co. (1983) Residues: Dithane M-45. (Compilation; unpublished study received May 13, 1983 under 707-78; CDL: 071599-A)
131898	Rohm & Haas Co. (1982) Study: Dithane M-45 Residue on Corn. (Compilation; unpublished study received Sep 6, 1983 under 707- 78; CDL:251204-A)
142522	Kryzwicki, K.; Wargo, R. (1983) Toxicity Report:[on Mithane M 45 DG Fungicide: Final Report: 83R 086A. Unpublished study prepared by Rohm and Haas Co. 9 p.
148228	Scribner, H. (1985) Genetic Toxicology Summary, Evaluation and Conclusions: Mancozeb. Unpublished study prepared by Rohm & Haas Co. 33 p.
148233	Chism, E. (1984) Dithane M-45; Microbial Mutagen Assay: [S-9 Prepared from Aroclor 1254 Induced Fischer 344 Rats]: Report No. 84R-0059. Unpublished study prepared by Rohm & Haas Co. 10 p.
148234	Chism, E. (1984) Dithane M-45; Microbial Mutagen Assay: [S-9 Prepared from Aroclor 1254 Induced B6C3F1 Mice]: Report No. 84R- 0060. Unpublished study prepared by Rohm and Haas Co. 11 p.
148235	McCarroll, N. (1984) Host Mediated Assay in Mice with Compound Dithane M-45: Final Report No. 84RC-025B (Definitive): Project No. 417-411. Unpublished study prepared by Hazleton Laboratories America, Inc. 56 p.
148236	McCarroll, N. (1985) Host Mediated Assay in Mice with Compound Dithane M-45: Final Report: Revised: Project No. 417-415. Unpublished study prepared by Hazleton Laboratories America, Inc. 37 p.
148237	Foxall, S.; Byers, M. (1985) Dithane M-45 CHO/HGPRT Gene Mutation Assay: Report No. 84R-0207. Unpublished study prepared by Rohm and Haas Co. 57 p.
148238	Byers, M. (1985) Dithane M-45 in vitro Unscheduled DNA Synthesis Assay: Report No. 84R-280. Unpublished study prepared by Rohm and Haas Co. 32 p.
148239	Sames, J.; McLeod, P.; Doolittle, D. (1984) Dithane M-45 in vivo Cytogenetic Study in Fischer-344 Rats: Report No. 84R-246. Un- published study prepared by Rohm and Haas Co. 47 p.

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149193	Ivett, J. (1985) Mutagenicity Evaluation of Dithane M-45 Fungicide Lot No. 0842 (TD 83-224) Rohm and Haas Protocol No. 83P-54 in an in vitro Sister Chromatid Exchange Assay in Chinese Hamster Ovary (CHO) Cells: Final Report: Rohm and Haas Report No. 84RC- 60: LBI Project No. 20990. Unpublished study prepared by Litton Bionetics, Inc. 38 p.
152696	Yeh, S. (1985) Distribution of Radiolabeled Mancozeb Metabolites in Soybeans: Technical Report No. 31L-85-18. Unpublished report prepared by Rohm and Haas Co. 53 p.
154192	O'Hara, G.; DiDonato, L. (1985) Dithane M-45 and Ethylenethiourea (ETU): 3 Month Dietary Study in Mice: Report No. 80R-124. Unpublished study prepared by Rohm & Haas Co. 533 p.
155843	Predmore, L.; Shaffer, S. (1986) Field Aged Mancozeb Residues on Alfalfa Hay Feeding Study in Lactating Dairy Cows: Final Report: ABC Study No. 33553. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 56 p.
155844	Jameson, C.; Shaffer, S. (1986) Residues of Mancozeb and Ethylenethiourea in Eggs and Edible Tissues from Hens Fed Field Aged Mancozeb Residues: Final Report: ABC Study No. 33552. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 54 p.
156715	Yeh, S. (1986) Distribution of Radiolabeled Mancozeb Metabolites in Sugar Beets: Report No. 31L-86-08. Unpublished study prepared by Rohm and Haas Co. 361 p.
157431	Rohm & Haas Co. (1964) Analytical Results of Dithane M-45 Residues. Unpublished compilation. 16 p.
157432	Rohm and Haas Co. (1964) Analytical Results of Dithane M-45 Residue:[Celery]. Unpublished compilation. 12 p.
159471	Hagan, J.; Fisher, J.; Baldwin, R. (1986) Subchronic Inhalation Toxicity Study in Rats: Mancozeb: Report No. 86R-003: Final Report. Unpublished study prepared by Rohm and Haas Co. 673 p.
159472	Satterthwaite, S. (1986) Analytical Reports of Mancozeb and ETU Residues for Processed Apple Samples: Tech. Report No. 310-86- 12. Unpublished study prepared by Rohm and Haas Co. in cooperation with Enviro-Bio-Tech, Ltd. 103 p.
159473	Satterthwaite, S. (1986) Analytical Reports of Mancozeb and ETU Residues for Processed Barley Samples: Tech. Report No. 310-86- 09. Unpublished study prepared by Rohm and Haas Co. in cooperation with EnviroBio-Tech, Ltd. 41 p.

MRID	Citation Reference
159474	Satterthwaite, S. (1986) Analytical Reports of Mancozeb and ETU Residues for Processed Corn Samples: Tech. Report No. 310-86-10. Unpublished study prepared by Rohm and Haas Co. in cooperation with Enviro-Bio-Tech., Ltd. 58 p.
159475	Satterthwaite, S. (1986) Analytical Reports of Mancozeb and ETU Residues for Processed Grape Samples: Tech. Report No. 310-86-08. Unpublished study prepared by Rohm and Haas Co. in cooperation with Enviro-Bio-Tech., Ltd. 123 P.
159476	Satterthwaite, S. (1986) Analytical Reports of Mancozeb and ETU Residues for Processed Peanut Samples: Tech. Report No. 310-86- 07. Unpublished study prepared by Rohm and Haas Co. in cooperation with Enviro-Bio-Tech., Ltd. 44 p.
159477	Satterthwaite, S. (1986) Analytical Reports of Mancozeb and ETU Residues for Processed Sugarbeet Samples: Tech. Report No. 310- 86-11. Unpublished study prepared by Rohm and Haas Co. in co- operation with Enviro-Bio-Tech., Ltd. 43 p.
159478	Ollinger, J.; Lyman, W.; Larkin, R. (1986) Food Processing Studies for Apples Treated with Mancozeb: Tech. Report No. 310-86-13. Unpublished study prepared by Rohm and Haas Co. in cooperation with National Food Laboratory. 90 p.
159479	Ollinger, J.; Lyman, W.; Larkin, R. (1986) Food Processing Studies for Grapes Treated with Mancozeb: Tech. Report No. 310-86-15. Unpublished study prepared by Rohm and Haas Co. in cooperation with National Food Laboratory. 97 p.
159480	Ollinger, J.; Lyman, W.; Larkin, R. (1986) Food Processing Studies for Potatoes Treated with Mancozeb: Tech. Report No. 310-86-16. Unpublished study prepared by Rohm and Haas Co. in cooperation with National Food Laboratory. 79 p.
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41901102	Pitt, J. (1991) Maneb and Mancozeb and their Metabolite Ethylene Thiourea: Magnitude of the Residue in Tomato: Lab Project Number ML89-0142-PEN: BR-89-23. Unpublished study prepared by Morse Laboratories, Inc. 420 p.
41903601	Stadler, J. (1990) Combined Chronic Toxicity/Oncogenicity Study with Mancozeb: Two-Year Feeding Study in Rats: Lab Project Number: 259-89. Unpublished study prepared by Dupont/ Haskell Laborato- ry. 2342 p.
41948401	Beavers, J.; Marselas, G.; Smith, G.; et al. (1991) Mancozeb: A One-Generation Reproduction Study with the Mallard (Anas platyrhynchos): Lab Project Number: 129-144: 89RC-0152. Unpublished Study prepared by Wildlife International Ltd. 196 p.
41976101	Haines, L. (1991) Mancozeb and ETU Storage Stability Study on Apples: Lab Project Number: 34-91-45. Unpublished study prepared by Rohm and Haas Co. and Enviro-Bio-Tech, Ltd. 149 p.
41981801	Shellenberger, T. (1991) Mancozeb: 18-Month Dietary Oncogenicity Study in Mice: Final Report: Lab Project Number: 85051: 86RC/ 0029. Unpublished study prepared by Tegeris Laboratories, Inc. 3207 p.
42034101	Stadler, J. (1991) Neuropathology Study in Rats with Mancozeb: Lab Project Number: 217/89. Unpublished study prepared by E. I. du Pont de Nemours & Co., Haskell Lab. 207 p.
42036901	Leparulo, M. (1991) 1990 Mancozeb and Metiram Apple Field Study: Storage Stability Study: Lab Project Number: ETU 91-06. Unpublshed study prepared by Technical Assessment Systems, Inc. 216 p.
42139901	Honeycutt, R. (1991) Determination of the Stability of Ethylene Thiourea Residues in Produce Bananas: Lab Project Number: 91- 120RA: 91-110RA. Unpublished study prepared by Morse Labs, Inc. 134 p.
42155901	Satterthwaite, S. (1988) Mancozeb and ETU Residues in Sweet Corn: Lab Project Number: 34A-88-84. Unpublished study pre- pared by Enviro-Bio-Tech, Ltd. 42 p.

MRID	Citation Reference
42556001	Singh, H. (1992) Determination of the Stability of Mancozeb and Ethylenethiourea in the Milk, Liver, Fat, Kidney, Muscles of Cows and Eggs, Liver, Fat, Kidney, Muscles and Gizzard of Chickens: Lab Project Number: TR-34-92-17: RH-41-51-89: Unpublished study prepared by Rohm and Haas Company. 123 p.
42560201	Honeycutt, R. (1992) Mancozeb Dislodgeable Foliar Residue and Worker Reentry Studies on Tomatoes: Supplement to MRID # 41836902: Lab Project Number: 91-118RA: 91-109. Unpublished study prepared by American Tech. & Analytical Service in cooperation with Agrisearch, Inc., Pan-Ag. Labs., Inc., McKenzie Labs., and Morse Labs., Inc. 3009 p.
42840501	Fisher, R.; Freedlander, R.; Hanauer, R.; et al. (1993) Mancozeb Metabolism Monograph: Lab Project Number: MZTF 93-1. Unpublished study prepared by Mancozeb Task Force. 251 p.
43140402	Pitt, J. (1994) Penncozeb: Magnitude of the Residue in Tomatoes: Lab Project Number: BR/92/20/1: BR/92/20. Unpublished study prepared by McKenzie Laboratories, Inc. 288 p.
43230701	Rhodes, J.; Downing, J.; Bielefeld, T. (1994) Early Life-Stage Toxicity of Mancozeb to the Fathead Minnow (Pimephales promelas) Under Flow-Through Conditions: Lab Project Number: 41148. Unpublished study prepared by ABC Labs., Inc. 247 p.
43294301	Pitt, J. (1994) Penncozeb and its Metabolite ETU: Magnitude of the Residue in Onions: Lab Project Number: BR-92-22-1: BR-92-22. Unpublished study prepared by McKenzie Labs, Inc.; California Ag Research, Inc. & P.U.P. Specialty Cropping. 396 p.
43336101	Pitt, J. (1994) Penncozeb and Its Metabolite ETU: Magnitude of the Residue in Potato: Lab Project Number: BR/92/21/1: BR/92/21. Unpublished study prepared by Elf Atochem North America and McKenzie Laboratories, Inc. 353 p.
43336102	Pitt, J. (1994) Manganese Ethylenebisdithiocarbamate and Its Metabolite Ethylene Thiourea: Magnitude of the Residue in Potato: Lab Project Number: BR/92/13/1: BR/92/13. Unpublished study prepared by Elf Atochem North America and McKenzie Laboratories, Inc. 309 p.
43336103	Pitt, J. (1994) Amendment 1 to: Manganese Ethylenebisdithiocarbamate and Its Metabolite Ethylene Thiourea: Magnitude of the Residue in Onions: Lab Project Number: BR/92/15/1: BR/92/15. Unpublished study prepared by Elf Atochem North America and McKenzie Laboratories, Inc. 26 p.

MRID	Citation Reference
43338701	Pitt, J. (1994) Manganese Ethylenebisdithiocarbamate and Its Metabolite Ethylene Thiourea: Magnitude of the residue in Onions: Lab Project Number: BR/92/15/1: BR/92/15: Unpublished study prepared by McKenzie Lab., Inc., California Ag Research, Inc., Pan Ag Labs. 456 p.
43357201	Honeycutt, R.; DeGeare, B. (1994) 1992 Mancozeb and Metiram Apple Residue Studies: Lab Project Number: 92/203RA: ETU/92/ APP: 93/310. Unpublished study prepared by Morse Lab., Inc., 1464 p.
43436701	Botts, D. (1994) Florida Mancozeb Celery Residue Studies: Final Report: Lab Project Number: TPR/110/93R. Unpublished study prepared by Third Party Registrations, Inc.; A. Duda & Sons, Inc.; and Morse Labs. 227 p.
43436801	Botts, D. (1994) Florida Mancozeb Carrot Residue Studies: Final Report: Lab Project Number: TPR/109/93R. Unpublished study prepared by Ag Consulting, Inc.; Morse Lab. 209 p.
43664701	Forbis, A. (1990) Acute Toxicity of Dithane M-45 Fungicide to *Selenastrum capricornutum* Printz: Final Report: Lab Project Number: 37735: 89RC-0045. Unpublished study prepared by ABC Labs, Inc. 208 p.
44023001	Biehn, W. (1996) Mancozeb: Magnitude of Residue on Carrots--1994 Trials: Lab Project Number: 03836: 3836: 3836.94-MCK 10. Unpublished study prepared by McKenzie Laboratories, Inc.; Michigan State University; University of Wisconsin. 321 p.
44023101	Robinson, P. (1996) Magnitude of the Residues of Mancozeb in the Raw Agricultural Commodity (RAC), The Edible Portion of Summer Squash, Following Eight Sequential Applications of Mancozeb at 2.5 LB AI/Acre to Summer Squash Plants: Final Report: Lab Project Number: ABG 95-0103: ABG PM 95-0103: 95ABG0101. Unpublished study prepared by Agri Business Group, Inc. and Morse Laboratories, Inc. 287 p.
44038801	Leppert, B. (1996) Magnitude of Mancozeb Residues in Cotton From In-Furrow Treatment: Final Report: Lab Project Number: SARS-93-20: ML93-0431-RAH: RH.1993-01. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Morse Laboratories, Inc. 413 p.
44051501	Leppert, B. (1996) Magnitude of Mancozeb Residues in Tomatoes: Final Report: Lab Project Number: SARS-95-31: ML95-0547-MCB: SARS-95-FL-31A. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Morse Laboratories, Inc. 312 p.

MRID	Citation Reference
44064001	Bennett, R.; Honeycutt, R. (1996) EBDC Residues--Commercial Apple Preparation: Lab Project Number: 94-403RA: ETU-94-APP: 95-514. Unpublished study prepared by Morse Labs., Inc. 496 p.
44074301	Robinson, P. (1996) Magnitude of the Residues of Mancozeb in the Raw Agricultural Commodity (RAC), The Edible Portion of Cucumber, Following Eight Sequential Applications of Mancozeb at 2.4 lb AI/Acre to Cucumber Plants: (Final Report): Lab Project Number: ABG PM 95-0102: 95ABG0100: 95ABG100. Unpublished study prepared by Agri Business Group, Inc. and Morse Labs, Inc. 312 p.
44074302	Robinson, P. (1996) Magnitude of the Residues of Mancozeb in the Raw Agricultural Commodity (RAC), The Edible Portion of Melon, Following Eight Sequential Applications of Mancozeb at 2.4 lb AI/Acre to Melon Plants: Lab Project Number: ABG PM 95-0104: 95ABG0101: 95ABG101. Unpublished study prepared by Agri Business Group, Inc. and Morse Labs, Inc. 375 p.
44080701	Singer, G. (1996) Magnitude of the Residue of Mancozeb in/on Field Corn and Corn Grown for Hybrid Seed, Forage, Grain, and Fodder: Final Report: Lab Project Number: AA950301: AA950301-5: AA950301-3. Unpublished study prepared by American Agricultural Services, Inc. and McKenzie Labs. 270 p.
44101101	Bennett, R.; Honeycutt, R. (1996) 1992 Mancozeb and Metiram Apple Processing Study: Final Report: Lab Project Number: 92-203RA-P: ETU-92-APP-P: 95-515. Unpublished study prepared by Morse Laboratories, Inc. and The National Food Laboratory. 1328 p.
44134201	Singer, G. (1996) Magnitude of the Residue of Mancozeb in/on Processed Commodities from Field Corn Grain or Grain Grown for Hybrid Seed: Final Report: Lab Project Number: AA950302: AA950302-01: AA950302.NE. Unpublished study prepared by American Agricultural Services, Inc. and Mckenzie Labs, Inc. 237 p.
44154601	Singer, G. (1996) Magnitude of the Residue of Mancozeb in/on Sweet Corn Ears, Forage, Grain, and Fodder: Final Report: Lab Project Number: AA950303: AA950303-01: AA950303-02. Unpublished study prepared by American Agricultural Services, Inc. and Mckenzie Labs, Inc. 342 p.
44159501	Mitchell, L.; Haberlein, D.; Beavers, J. et al. (1996) Mancozeb (Dithane): A Reproduction Study with the Northern Bobwhite (*Colinus virginianus*): Amended: Lab Project Number: 422-101. Unpublished study prepared by Wildlife International Ltd. 219 p.

MRID	Citation Reference
44167901	Leppert, B. (1996) Magnitude of Mancozeb Residues in Potatoes: Final Report: Lab Project Number: SARS-95-30: ML95-0546-MCB: SARS-95-NC-30. Unpublished study prepared by Stewart Agricultural Research Services, Inc and Morse Labs., Inc. 471 p.
44238001	Pelfrene, A. (1997) Mancozeb: Reproduction in the Bobwhite Quail: Reissued Report: Lab Project Number: PWT 99/920944: PWT 99. Unpublished study prepared by Huntingdon Life Sciences Ltd. 383 p.
44283401	Chetram, R.; Christensen, G.; Goodman, V. et al. (1997) Nontarget Terrestrial Plant Phytotoxicity Studies Using a 9%/60% WP Co-formulation of AC 336379 (Dimethomorph) and Mancozeb: (Final Report): Lab Project Number: 954-96-107: 954-96-108: 954-96-149. Unpublished study prepared by ABC Laboratories California. 250 p.
44283402	Canez, V.; Christensen, G.; Hughes, J.; et al. (1997) Effects of a 9%/60% WP Co-formulation of AC 336379 (Dimethomorph) and Mancozeb on the Growth of *Navicula pelliculosa*, *Selenastrum capricornutum*, *Anabaena flosaquae*, *Skeletonema costatum*, and *Lemna gibba*: (Final Report): Lab Project Number: 954-96-113: 954-96-166: 954-96-111. Unpublished study prepared by Carolina Ecotox. Inc. 457 p.
44524101	Esterly, D. (1998) Recalculation of the ETU Soil Half-Life in California Soil Dissipation Studies of Mancozeb Supplement No. 1 to MRID 40923601: Lab Project Number: MTF-98-02. Unpublished study prepared by E.I. du Pont de Nemours and Co. 43 p.
44629501	Pitt, J. (1998) Frozen Storage Stability of Mancozeb and ETU Residues in Potato: Lab Project Number: BR-92-41: BR-92-41-1: MTF-88AM-004. Unpublished study prepared by McKenzie Laboratories, Inc. 180 p.
44629502	Pitt, J. (1998) Frozen Storage Stability of Mancozeb and ETU Residues in Tomato: Lab Project Number: BR-92-40: BR-92-40-1: MTF-88AM-004. Unpublished study prepared by McKenzie Laboratories, Inc. 179 p.
44725101	Prochaska, L. (1998) Magnitude of Mancozeb Residues in Sugar Beets: Lab Project Number: SARS-96-03: ML96-0655-MCB: SARS-96-CO-03. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Morse Laboratories, Inc. 424 p. {OPPTS 860.1500, 860.1380}
44725501	Prochaska, L. (1998) Magnitude of Mancozeb Residues in Onion (Dry Bulb): Final Report: Lab Project Number: ML96-0653-MCB: 63552: SARS-96-02. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Morse Laboratories, Inc. 253 p.

MRID	Citation Reference
44725601	Robinson, P. (1997) Magnitude of the Residues of Mancozeb in the Raw Agricultural Commodity (RAC), the Edible Portion of Carrots, Following Ten Sequential Applications of Mancozeb at 1.6 LB AI/Acre to Carrot Plants: Lab Project Number: 96ABG0100: 96ABG100: ABG PM970100. Unpublished study prepared by Agri Business Group, Inc. and Morse Laboratories, Inc. 254 p. {OPPTS 860.1500}
44725701	Koppatschek, F. (1998) Magnitude of the Residues of Mancozeb in the Raw Agricultural Commodity (RAC), the Edible Portion of Cranberries, Following Three Sequential Applications of Mancozeb at 4.8lb AI/Acre to Cranberry Plants: Lab Project Number: 96ABG0102: 96ABG102: ABG PM970102. Unpublished study prepared by Morse Laboratories, Inc. and Agri Business Group, Inc. 224 p. {860.1500}
44725901	Prochaska, L. (1998) Magnitude of Mancozeb Residues in Pears: Lab Project Number: 63552: SARS-96-01: ML96-0654-MCB. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Morse Laboratories, Inc. 399 p.
44726001	Koppatschek, F. (1998) Magnitude of the Residues of Mancozeb in the Raw Agricultural Commodity (RAC), Whole Bananas, Following Ten Sequential Applications of Mancozeb at 2.4lb AI/Acre to Banana Plants: Lab Project Number: 96ABG0104: 96ABG104: ABG PM970104. Unpublished study prepared by Agri Business Group, Inc. and Morse Laboratories, Inc. 457 p. {OPPTS 860.1500}
44728301	Thompson, D. (1998) Mancozeb: Magnitude of Residue on Ginseng: Lab Project Number: 00992: 00992.92-AZR01: 0992.92-MCK01. Unpublished
44729901	Thompson, D. (1998) Mancozeb: Magnitude of Residue on Sugar Apple: Lab Project Number: 03130: 03130.95-MCK02: 03130.95-MOR05. Unpublished study prepared by IR-4 Project. 583 p. {OPPTS 860.1500}
44730801	Koppatschek, F. (1998) Magnitude of the Residues of Mancozeb in the Raw Agricultural Commodity (RAC), the Edible Portion of Grapes, Following Six Sequential Applications of Mancozeb at 2.0 lb AI/Acre to Grape Plants: Lab Project Number: 96ABG101: 96NY103: 96PA104. Unpublished study prepared by Agri Business Group, Inc., and Morse Laboratories, Inc. 266 p. {OPPTS 860.1500}
44747501	Koppatschek, F. (1998) Magnitude of the Residues of Mancozeb in the Raw Agricultural Commodity (RAC), the Edible Portion of Asparagus, Following Four Sequential Applications of Mancozeb at 1.6 LB AI/Acre to Asparagus Plants: Lab Project Number: 96ABG0103: METH-17: GL-13B. Unpublished study prepared by Agri Business Group, Inc. 203 p. {OPPTS 860.1500}

MRID	Citation Reference
44802501	Koppatoschek, F. (1999) Magnitude of Residues of Mancozeb in the Raw Agricultural Commodity (RAC), Wheat Hay, Seed and Straw, Following Three Sequential Applications of Mancozeb at 1.6 Lb. AI/Acre to Wheat Plants: Lab Project Number: 97ABG0105: 97ABG105: 97SC101. Unpublished study prepared by Agri Business Group, Inc. 472 p.
44950502	Madsen, T.; Leak, T. (1998) Acute Toxicity of Dithane/RH-117,281 DG Blend to *Daphnia magna*: Lab Project Number: 44179-97: 97RC-0068. Unpublished study prepared by ABC Laboratories, Inc. 79 p.
44950503	Rhodes, J.; Bucksath, J. (1998) Acute Flow-Through Toxicity of Dithane/RH-117,281 DG Blend to Rainbow Trout (*Oncorhynchus mykiss*): Lab Project Number: 43357: 97RC-0128: 95P-278. Unpublished study prepared by ABC Laboratories, Inc. 110 p.
44950504	Milligan, D. (1997) Dithane/RH-117,281 DG Blend (8:1): Laboratory Oral and Contact Test with the Honeybee, *Apis mellifera*: Final Report: Lab Project Number: 97-071-1007: 97RC-0070: 1007.030.265. Unpublished study prepared by Springborn Laboratories AG. 48 p.
44959601	Graves, D. (1999) Dissipation of Dislodgeable Foliar Residues of Mancozeb Applied to Grapes: Lab Project Number: 34-99-105: 34P-98-60: 3101.12. Unpublished study prepared by Research for Hire, Inc. and EN-CAS Analytical Laboratories. 351 p. {OPPTS 875.2100}
44959602	Graves, D. (1999) Dissipation of Dislodgeable Foliar Residues of Mancozeb Applied to Apples: Lab Project Number: 34P-98-59: 34-99-56: ENC-3/98. Unpublished study prepared by ACDS Research, Inc. and EN-CAS Analytical Laboratories. 499 p. {OPPTS 875.2100}
44959603	Graves, D. (1999) Dissipation of Dislodgeable Foliar Residues of Mancozeb Applied to Tomatoes: Lab Project Number: 34P-98-61: TR 34-99-108: GR98-323. Unpublished study prepared by Grayson Research, LLC. and Keystone Analytical Laboratories. 384 p. {OPPTS 875.2100}
44961701	Graves, D. (1999) Dissipation of Dislodgeable Foliar Residues of Mancozeb Applied to Greenhouse Tomatoes: Lab Project Number: TR 34-99-157: 34P-99-04: ENC-2/98. Unpublished study prepared by Grayson Research LLC and Keystone Analytical Laboratories. 349 p. {OPPTS 875.2100}
45736501	Kool, P. (1999) Penncozeb Technical Manufacturing Process Rotterdam Site: Final Report: Lab Project Number: ATO DL 99-032: DL 99-032. Unpublished study prepared by Elf Atochem Agri B.V. 42 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1670}

MRID	Citation Reference
45736502	Goodman, M.; Wright, J.; Harlass, M. (1998) Penncozeb Technical--Enforcement Analytical Method: Lab Project Number: KP-98-42: QC9842R0.QTR. Unpublished study prepared by Elf Atochem North America, Inc. 14 p. {OPPTS 830.1800}
45736503	Goodman, M. (1999) Penncozeb Technical: Physical and Chemical Properties: Lab Project Number: KP-98-27: QC9827R0.QTR. Unpublished study prepared by Elf Atochem North America, Inc. 32 p. {OPPTS 830.6302, 830.6303, 860.6304, 830.6313, 830.6314, 830.6316, 830.6317, 830.6319, 830.6320, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840, 830.7950}
45744501	Volkel, W. (2001) Degradation Rate of (Carbon 14)-Mancozeb in Three Soils Incubated Under Aerobic Conditions: Lab Project Number: 773346: TR34-01-03. Unpublished study prepared by RCC Ltd. 32 p.
45750501	Felperlaan, M. (1998) Mancozeb Technical Preliminary Analyses of Five Representative Samples: Lab Project Number: ATO DL 98-045: DL 98-045. Unpublished study prepared by Elf Atochem Agri B.V. 138 p. {OPPTS 830.1700}
45910401	Zok, S. (2001) Acute Toxicity Study on the Rainbow Trout (*Oncorhynchus mykiss Walbaum 1792*) in a Static System (96 Hours): Ethylenethiourea (ETU): Lab Project Number: 12F0533/005042: 2001/1001877: PCP06082. Unpublished study prepared by BASF Aktiengesellschaft. 44 p.
45910402	Hisgen, M. (2000) Determination of the Acute Effect on the Swimming Ability of the Water Flea *Daphnia magna Straus*: Ethylenethiourea (ETU): Lab Project Number: 00/0533/50/1: 2000/1017216: PCP05988. Unpublished study prepared by BASF Aktiengesellschaft. 27 p.
45934702	Rhodes, J. (2000) Acute Toxicity of Dithane M-45 to the Bluegill Sunfish (*Lepomis macrochirus*) Determined Under Flow-Through Test Conditions: Lab Project Number: 46041: 00RC-0115. Unpublished study prepared by ABC Laboratories, Inc. 75 p. {OPPTS 850.1075}
46204301	Volkel, W. (1995) [^{14}C]-Mancozeb: Degradation and Metabolism in Aquatic Systems. Project Number: 361462. Unpublished study prepared by RCC Umweltchemie Ag. 156 p.

Appendix E

PLACEHOLDER FOR GENERIC DATA CALL-IN (DCI)

This is a placeholder for the generic data call-in, which 1ists confirmatory studies for the active ingredient mancozeb that must be conducted as a condition of mancozeb's continued registration. The DCI will be issued at a future date.

Appendix F

PLACEHOLDER FOR PRODUCT SPECIFIC DATA CALL-IN (PDCI)

This is a placeholder for the product specific generic data call-ins, which 1ist studies necessary for the reregistration of products containing the active ingredient mancozeb. The PDCI will be issued at a future date.

Appendix G

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to

Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Forty-eight products were found which contain Mancozeb as an active ingredient. These products have been placed into five batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

1. Batch 4 products may be supported only by data performed with EPA Reg. No. 241-395.

2. Batch 5 products may be supported only by data performed with EPA Reg. No. 100-944.

Batch #	EPA Reg. No.	Percent Active Ingredient
1	829-286	80
	1001-65	80
	1001-77	75
	1812-415	80
	2217-426	80
	4581-357	80
	4581-358	80
	4581-370	75
	48273-20	80
	62719-387	80
	62719-388	80
	62719-401	70
	62719-402	75
	62719-422	80
	62719-423	80
2	58185-31	64
	58185-32	64
3	2935-496	6
	2935-539	8
	2935-541	6

Batch #	EPA Reg. No.	Percent Active Ingredient
	3468-57	8
	11682-35	6
4	241-383	60
	241-395	60
	241-411	60
5	100-944	9.6
	100-1158	5.7
No Batch	100-803	64
	264-972	6
	264-977	6
	264-978	6
	554-148	16
	1812-360	15
	1812-414	75
	1812-416	37
	3468-59	8
	4581-375	88
	4581-394	37
	4581-397	30.4
	42056-6	50
	42056-20	22.8
	62719-396	37
	62719-398	32
	62719-418	60
	62719-441	66.7
	71711-8	6

Appendix H

LIST OF REGISTRANTS SENT DATA CALL-IN (DCI)

This is a placeholder for the list of registrants, which will be generated at a future date, just before the DCI is mailed.

Appendix I

LIST OF ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available (in PDF format and require the Acrobat reader) at the EPA internet site: http://www.epa.gov/opprd001/forms/ .

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice98-1)	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' website.

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

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

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

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

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

   a. Date of receipt;
   b. EPA identifying number; and
   c. Product Manager assignment.

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

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