United States Environmental Protection Agency

Prevention, Pesticides and Toxic Substances (7508C)

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September 2005

Reregistration Eligibility Decision for Ferbam

Reregistration Eligibility Decision (RED) Document for **Ferbam**

List B

Approved by: _____

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Date: September 2005

Table of Contents

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Glossary of Terms and Abbreviations

ai	Active Ingredient
AR	Anticipated Residue
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
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
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
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 submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient 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 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard

Abstract

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered uses of the fungicide ferbam [ferric dimethyldithiocarbamate]. The Agency has determined that ferbam is eligible for reregistration.

Ferbam is a fungicide used on citrus, pome and stone fruits, grapes, berries, and tobacco. It has 27 tolerances which have been reassessed, and 18 of those tolerances are proposed for revocation. There are no residential uses of ferbam, and it has no dietary or occupational risks of concern when appropriate personal protective equipment is worn. There are ecological risks of concern to non-target terrestrial and aquatic organisms, and worker risks.

To address the ecological and occupational risks of concern, label changes and the following mitigation is required for ferbam to be eligible for reregistration: delete aerial application for all uses, the registrant will voluntarily cancel use on three crops, reduce maximum single application rates for pome fruits and citrus, limit the number of ferbam applications per year on all crops, and use scenario-specific personal protective equipment. In addition, where there are data gaps, data must be generated to confirm the reregistration eligibility decision documented in this RED.

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 to the EPA. 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 (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 that by August 2006, EPA must review all tolerances in effect on the day before the enactment of the FQPA, which was August 2, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including 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.

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the

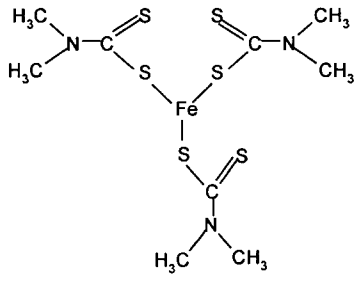
cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Ferbam belongs to the dithiocarbamate group of fungicides which have neuropathy as a common toxic effect. In December 2001 EPA concluded, based on the recommendations of the Science Advisory Panel (SAP), that the neuropathy induced by the dithiocarbamates can not be linked to a common mechanism of toxicity (Memorandum titled, The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity, From: Marcia Mulkey to Lois Rossi, dated December 19, 2001). Further, EPA has concluded that the dithiocarbamates should not be included in the cumulative assessment of the N-methyl carbamates since they do not share acetylcholinesterase inhibition as their principal mechanism of toxicity. Thus, for the purposes of this reregistration determination, EPA has assumed that ferbam does not share a common mechanism of toxicity with other pesticides.

The document consists of six sections: Section I contains the regulatory framework for reregistration and tolerance reassessment; Section II provides a profile of the use and usage of the chemical; Section III gives an overview of the human health and environmental effects risk assessments based on data, public comments, and other information received; 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 as well as data requirements; and Section VI comprises the appendices which list related information and supporting documents. The preliminary and revised risk assessments for ferbam are available in the Public Docket, under docket number OPP-2004-0337 and on the Federal Docket Management System (FDMS) web page, http://www.regulations.gov.

II. Chemical Overview

A. Chemical Identification

Chemical Structure:



Common Name: Ferbam

Trade Name: Ferbam Granuflo

Chemical Name: [ferric dimethyldithiocarbamate]

CAS Registry Number: 14484-64-1

OPP Chemical Code: 034801

Case Number: 2180

Molecular Weight: 416.50

Empirical Formula: $C_9H_{18}FeN_3S_6$

Basic Manufacturers: Taminco, Inc.

Ferbam is a fine black powder which decomposes at 180 degrees C, and has a density of 1.36 g/mL at 20 degrees C and vapor pressure of $<8.6 \times 10^{7}$ Torr. It has moderately low solubility in water (120 ppm) and is soluble in acetone, acetonitrile, chloroform, and pyridine. Ferbam tends to decompose upon exposure to heat and moisture with prolonged storage.

Ferbam has been registered in the United States since 1948 for use as a fungicide. The Agency conducted a review of the scientific data underlying pesticide registrations and identified missing or inadequate studies. A Phase IV Data Call-In (DCI) was issued in October 1991. Subsequent data call-ins were issued in September 1993, March 1995, October 1995, and February 1996. This Reregistration Eligibility Decision (RED) reflects an assessment of all data submitted to date.

Currently, there are four products containing ferbam registered under Section 3 of FIFRA. Additionally, there are three Special Local Need (SLN) registrations including use on cranberries in New Jersey and Massachusetts, and use on mangos in Florida. This RED evaluates risk from all currently registered uses of ferbam.

B. Use Profile

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

Type of Pesticide: Ferbam is a broad-spectrum fungicide.

Summary of Use: It is registered for use on citrus crops, a variety of pome and stone fruits, berries, ornamentals, conifers, and tobacco. There are no residential uses of ferbam.

Target Organisms: Anthracnose, downy mildew, leaf spots, Botrytis, fruit rots, and rusts.

Use Classification: General use

Formulation Types: Water dispersible granule (76% active ingredient).

Application Methods: Application methods are aerial, airblast, and groundboom.

Application Rates: The maximum label application rate is 19.76 pounds active ingredient/acre (lb ai/A) for rough lemon nursery stock, although a higher application rate is on labels for a SLN registration for spot treatment on cranberries. Refer to Table 1 for additional application rates:

Table 1. Application Rates for Ferbam

Crop	Maximum Single Application Rate (lb ai/A)	Maximum Application Rate per Season (lb ai/A)
Citrus (grapefruit, lemons, limes, oranges, tangelos, tangerines)	11.4	34.2
Apples	6.08	Not Specified
Pears	4.56	Not specified
Cranberries (groundboom)	4.56	22.8
Peaches and Nectarines (dormant use only)	3.42	6.84
Grapes	3.04	9.12

Use Locations: Ferbam is primarily used in Massachusetts, New Jersey, and Florida.

Tolerances: Currently, there are 27 ferbam tolerances. The crops for which the Agency will propose to revoke tolerances and/or cancel uses include apricots, asparagus, beans, blueberries, blackberries, youngberries, cabbage, caneberries, cucumbers, lettuce, papaya, peas, squash, and tomatoes, since these uses are not being supported by the registrant.

Annual Pounds Used: Approximately 160,000 pounds.

Percent Crop Treated: Ferbam comprises approximately10% of the crop treated for tangerines and 5% or less for all other crops.

III. Summary of Ferbam Risk Assessments

The following is a summary of EPA's human health and ecological risk findings and conclusions for ferbam, as presented fully in the documents "Revised Ferbam HED Risk Assessment for Reregistration Eligibility Decision (RED) Document " written by R. Daiss, (4/19/05), "Addendum to the Risk Assessment and Recommendations for the Reregistration Eligibility Decision (RED) for Ferbam", and "EFED Error Correction for the RED Chapter for Ferbam" written by N.E. Federoff and J. Meléndez (2/23/05).

The purpose of this section is to highlight the key features and findings of the risk assessments in order to help the reader better understand the risk management decisions reached by the Agency. While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket http://epa.gov/edockets (docket number OPP-2004-0337) and may also be accessed on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

A. Human Health Risk Assessment

Although the Agency assumes no common mechanism of toxicity with other pesticides, ferbam is similar in its toxicity to the structurally related compounds thiram and ziram. Also, there are similarities in the metabolism of ferbam, thiram, and ziram. Thus, studies from the ziram and thiram databases were used as surrogates for those lacking in the ferbam database.

1. Toxicity

Ferbam is a relatively low toxicity chemical. It has low acute toxicity (Category III) via the oral and dermal routes, and moderate (Category II) acute toxicity via the inhalation route. It is a slight eye irritant and weak dermal sensitizer. Ferbam is not considered to be mutagenic, and a developmental neurotoxicity (DNT) study is not required.

Although there are limited evidence and data on developmental neurotoxicity in the ferbam reproduction studies, the DNT study for thiram helps inform ferbam's developmental neurotoxicity. The No Observable Adverse Effect Level (NOAEL) from thiram's DNT study is 1.4 mg/kg/day. This study has been used to establish the acute dietary RfD for females, aged 13-49, and short-term and intermediate term dermal endpoints. Based on information available on developmental neurotoxicity for thiram, the Agency has determined that a DNT study for ferbam is not required.

The Agency has set an acute reference dose (RfD) of 0.05 mg/kg/day for population subgroups other than females aged 13-49, based on a NOAEL of 5 mg/kg/day; effects observed at the LOAEL were impaired functional observational batteries (FOB) from an acute neurotoxicity study of thiram in rats. Additionally, the Agency has set a chronic RfD of 0.015 mg/kg/day based on a NOAEL of 1.5 mg/kg/day; effects observed at the LOAEL were decreased body weight gain and increased organ weight. The RfD is based on a combined chronic toxicity/carcinogenicity study of thiram in rats and a 100-fold inter-/intra-species uncertainty factor (see Table 2).

Table 2. Summary of Toxicological Doses and Endpoints for Ferbam			
Exposure Scenario	**Dose Used in Risk Assessment, UF=100**	**Special FQPA SF = 1x and Level of Concern (LOC) for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary All Populations (except females age 13-49)	NOAEL= 1.5 mg/kg/day Acute RfD = 0.05 mg/kg/day	aPAD = acute RfD / FQPA SF = 0.05 mg/kg/day	Acute Neurotoxicity Study - Rat LOAEL = 150 mg/kg/day based on FOB effects (lethargy, lower temperature, reduced startle response, no tail pinch response) and reduced motor activity
Acute Dietary (Females age 13-49)	NOAEL = 1.4 mg/kg/day Acute RfD = 0.014 mg/kg/day	acute RfD / FQPA SF = 0.014 mg/kg/day	Developmental Neurotoxicity Study - Rat LOAEL = 3.7 mg/kg/day based on increases in motor activity seen in female offspring on PND 17
Chronic Dietary All Populations	NOAEL= 1.5 mg/kg/day Chronic RfD = 0.015 mg/kg/day	cPAD = chronic RfD / FQPA SF = 0.015 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity Study - Rat LOAEL = 7.3 mg/kg/day based on changes in hematology, clinical chemistry, incidences of bile duct hyperplasia, and reduction in mean body weight gain
Incidental Oral All Durations	Endpoints of concern were not selected for incidental oral exposure scenarios (short and intermediate terms), since there are no residential uses (e.g., turf) supported for ferbam.		
Dermal Short-Term (1-30 days) Intermediate-Term (1-6 mo)	Oral study NOAEL=1.4 mg/kg/day (Dermal absorption factor = 1%)	Residential LOC for MOE = N/A Occupational LOC for MOE = 100	Developmental Neurotoxicity Study - Rat LOAEL = 3.7 mg/kg/day based on increases in motor activity seen in female offspring on PND 17
Inhalation All durations	NOAEL= 1.5 mg/kg/day Inhalation Absorption Rate = 100%	Residential MOE =N/A Occupational MOE = 100	Combined Chronic Toxicity/Carcinogenicity Study - Rat LOAEL = 7.3 mg/kg/day based on changes in hematology, clinical chemistry , incidences of bile duct hyperplasia, and reduction in mean body weight gain
Cancer Oral, Dermal, Inhalation	Not likely to be carcinogenic in humans		

There were no tumor effects observed in the ferbam studies; therefore, no cancer assessment was done. Thiram is classified as "not likely to be carcinogenic to humans" and ziram is classified as "suggestive evidence of carcinogenicity to humans" with no quantitative risk assessment.

FQPA Special Safety Factor.

The Food Quality Protection Act (FQPA) of 1996 directs EPA, in setting pesticide tolerances, to use an additional tenfold margin of safety to protect infants and children, taking into account the potential for pre- and postnatal toxicity and the completeness of the toxicology and exposure databases. The statute authorizes EPA to modify this tenfold FQPA safety factor with a different FQPA factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

After evaluating hazard and exposure data for ferbam, EPA reduced the default 10x FQPA safety factor to 1x. The toxicity database for ferbam, which is bridged to thiram, includes acceptable developmental and reproductive toxicity studies, and there is no evidence in the developmental toxicity study of susceptibility following *in utero* exposure. Also, the Agency has a low level of concern and no residual uncertainties regarding exposure or concerns for the effects seen in the developmental toxicity studies after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment. Therefore, the 10X FQPA special safety factor was reduced to 1X.

Database Uncertainty Factor

The bridged toxicological database for ferbam is considered complete, and the Agency has concluded that there is no need for a database uncertainty factor.

2. Dietary Exposure and Risk from Food and Water

(For a complete discussion, see Section 6.0 of the Revised Ferbam HED Risk Assessment for Reregistration Eligibility Document (RED) by R.Daiss).

Dietary risk assessment incorporates both exposure to and toxicity of a given pesticide. The risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the special FQPA Safety Factor which was reduced to 1x for ferbam; therefore the PAD = RfD. EPA is concerned when estimated dietary risk exceeds 100% of the PAD.

The residue data for processed commodities of food/feed crops that are from presently registered use sites have been evaluated and deemed adequate by the Agency. Based on these data, the Agency intends to revise some tolerances and revoke several crop tolerances for uses which the registrant will no longer support. All crops on current labels were included in the risk assessments, even though the registrant intends to cancel various uses. As a result, the ferbam risk assessments are conservative.

EPA has determined that, due to their similarity in metabolism, thiram and ziram data are appropriate for use in the ferbam dietary exposure assessments. Therefore, where no ferbam-specific

residue data are available, acceptable ziram and thiram field trial data have been translated to ferbam (i.e., for common crops with comparable application rates, number of applications, and post-harvest intervals (PHIs)). Available chemical specific data from processing studies were used for processed commodities. An 85% washing reduction factor from a ziram peach processing/washing study was applied to all assessed commodities. In addition, the percent crop treated (CT) was used for all commodities for which data were available, and where no percent CT data were available, the dietary analyses assumed 100% CT.

The most sensitive acute endpoint from the ferbam, ziram and thiram databases was selected from a thiram DNT study. This endpoint is appropriate only for the population subgroup females of child bearing age (ages 13 - 49). The endpoint for the U.S. population and other population subgroups was selected from an acute neurotoxicity study. For the dietary (food and water) assessment, the aPAD is not exceeded for any population subgroups and the percent of aPAD fits within the Agency's risk cup. For more detail on the endpoint selection refer to the "Addendum to the Risk Assessment and Recommendations for the Reregistration Eligibility Decision (RED) for Ferbam" dated 9/26/05 by R. Daiss.

As there is potential for concurrent exposure to ferbam via food and water, the combined exposures are estimated for the acute (aggregate) and chronic (aggregate) dietary assessment.

Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (short term) and chronic (long term) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate the exposure. No water monitoring data were available; therefore Tier II Estimated Drinking Water Concentrations (EDWCs) of thiram were calculated using PRZM/EXAMs (surface water) and Tier I EDWCs were calculated utilizing SCIGROW (ground water). Modeling is carried out in tiers of increasing refinement, but is designed to provide high-end estimates of exposure.

EDWCs are calculated for thiram instead of ferbam because the environmental fate data indicate that the parent compound either biodegrades or undergoes hydrolysis to thiram in 31 minutes or less. The EDWCs for thiram are calculated based on a maximum application rate of ferbam of 19.8 lb ai/A with the Florida citrus (rough lemon nursery stock) scenario for surface water. The estimated acute concentration in surface water is 80.57 ppb of thiram, which represents a one in ten year highest concentration from a vulnerable site. The estimated chronic concentration is 2.5 ppb, which represents a high-end annual mean value over a 30-year period, also at a vulnerable site. The SCIGROW model generated a Tier I ground water EDWC of 0.02 ppb of thiram, which is suitable for acute and chronic estimates. The surface water values were used as high-end estimates for dietary risk (see Table 3).

Table 3. Drinking Water EDWCs for Thiram from Ferbam Use		
Drinking Water Source	**Acute (ug/L)**	**Chronic (ug/L)**
Surface Water	81	2.5
Ground Water	0.02	0.02

Acute Dietary Risk

The acute dietary risk assessment was conducted for all ferbam food uses and drinking water. Acute dietary risk is calculated based on quantity of food eaten in one day and maximum, or high-end, residue values in the food. Drinking water residues are derived from Tier I and Tier II aquatic models and integrated into the dietary exposure models. As noted above, EDWCs were assessed for thiram, instead of ferbam, because the environmental fate data indicate that the parent compound degrades rapidly to thiram. A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) is below the Agency's level of concern.

Field trial data for ferbam, ziram and thiram were used to estimate ferbam residues in or on most commodities. Tolerance level residues were assumed for a few commodities that had no field trial data to ensure that EPA would not underestimate potential exposure. No monitoring data were available.

EPA evaluated the acute dietary risks using the Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM-FCID™) Version 2.03. The acute dietary risk estimates fell below EPA's level of concern for the general U.S. population and all population subgroups, including infants and children at the 99.9th percentile of exposure. The most highly exposed subgroup was children 1-2 years old, at 68% of the aPAD. Table 4. illustrates the acute risk estimates for the combined acute dietary (food and water) exposures.

Table 4. Ferbam Acute Dietary (Food and Water) Exposure Estimate and Percent of Acute PAD			
Population Subgroup	**aPAD (mg/kg/day)**	**DEEM**	
		Exposure (mg/kg/day) 99.9th percentile	**% aPAD 99.9th percentile**
General U.S. Population	0.05	0.0108	22
All Infants (< 1 year old)	0.05	0.0183	37
Children 1-2 years old	0.05	0.0338	68
Children 3-5 years old	0.05	0.0236	47
Children 6-12 years old	0.05	0.0127	25
Females 13-49 years old	0.01*	0.0021	44
*Based on the thiram DNT study NOAEL of 1.4 mg/kg/day			

The risk estimate for the population subgroup of children ages 1 - 2 is a conservative, high-end value because of several factors, including: tolerances level residues were used for some crops, 100% crop treated was assumed for various crops, and the EDWCs are calculated using a vulnerable site for the modeling parameter.

For women of child bearing age, the thiram DNT study was chosen to provide a protective endpoint for acute dietary assessment. The DEEM acute dietary exposure estimate for the population subgroup of females age 13 - 49 is 44% of the aPAD, which is below EPA's level of concern. For more detail on the acute dietary endpoints, refer to the "Addendum to the Risk Assessment and Recommendations for the Reregistration Eligibility Decision (RED) for Ferbam" dated 9/26/05 by R. Daiss.

Chronic Dietary Risk

Chronic dietary risk is calculated by using the average consumption values for foods and average residue values on those foods. A risk estimate that is less than 100% of the chronic Population Adjusted Dose (cPAD) (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) is below the Agency's level of concern. An uncertainty factor of 100x was applied to the chronic dietary assessment for inter- and intraspecies variations, and the FQPA safety factor was reduced to 1x as discussed in the dietary risk section above. The assessment incorporated tolerance level food residues adjusted for processing, washing factors, and % CT, as well as a point estimate for water residues.

The ferbam chronic dietary exposure assessment was conducted using the DEEM-FCID™ Model Version 2.03. In this analysis the chronic dietary exposure and risk estimates resulting from food intake were determined for the general U.S. population and various population subgroups.

The resulting food and drinking water risk estimates using the DEEM-FCID™ Model were 5% or less of the cPAD for the U.S. population and all population subgroups. Children 1-2 years old were the most highly exposed population subgroup, at an estimated 5% of the cPAD (see Table 5).

Table 5. Ferbam Chronic Dietary and Drinking Water Exposure Estimate and Percent of cPAD

Population Subgroup	cPAD (mg/kg/day)	DEEM	
		Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.015	0.0002	1
All Infants (< 1 year old)	0.015	0.0006	4
Children 1 - 2 years old	0.015	0.0007	5
Children 3 - 5 years old	0.015	0.0005	4
Children 6 - 12 years old	0.015	0.0003	2
Youth 13 - Adults 50+ years old	0.015	0.0002	1

3. Chronic Aggregate Risk

There are no residential uses for ferbam; as a result, a residential risk assessment was not conducted and the aggregate risk is the same as the dietary (food and water) risk above.

4. Occupational Exposure and Risk

(For a complete discussion, see section 9.0 of the Revised Ferbam HED Risk Assessment for Reregistration Eligibility Document (RED) by R. Daiss dated 4/19/05).

People can be exposed to a pesticide while working through handling, mixing, loading, or applying a pesticide, and reentering a treated site. Handler and worker risks are measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) taken from animal studies. Generally, MOEs greater than 100 do not exceed the Agency's level of concern.

For ferbam, only short and intermediate-term occupational exposures are expected based on label specified use patterns. For the occupational assessment, the most sensitive endpoint was selected from the thiram DNT study. The NOAEL from the acute thiram DNT is 1.4 mg/kg/day based on females ages 13 - 49. Thus, the weight assumption for dermal exposure was changed from 70 kg to 60 kg to account for use of a dermal endpoint selected based on effects to females. For a more detailed discussion of the occupational assessment using the thiram endpoint refer to the "Addendum to the Risk Assessment and Recommendations for the Reregsitration Eligibility Decision (RED) For Ferbam" dated 9/26/05 by R. Daiss.

In addition, short and intermediate term dermal endpoints were selected from a thiram 21-day dermal toxicity study in rabbits. The NOAEL is 300 mg/kg/day and the LOAEL is 1000 mg/kg/day based on decreases in body weight and food consumption as well as alterations in clinical chemistry. The short and intermediate endpoints for inhalation exposure are based on a combined chronic toxicity/carcinogenicity study in rats. The NOAEL is 1.5 mg/kg/day and the LOAEL is 7.3 mg/kg/day based on changes in hematology, clinical chemistry, incidences of bile duct hyperplasia, and reduction in mean body weight gain. These endpoints were used for assessment prior to the submission of the thiram DNT study and formed the basis of the occupational assessment in the Revised Ferbam HED Risk Assessment for the Reregistration Eligibility Document (RED) dated 4/19/05 by R. Daiss.

Occupational Handler Summary

Exposure analyses were performed using the Pesticide Handlers Exposure Database (PHED). The target MOE for workers is 100, which includes the standard safety factors of 10X for intraspecies variability (differences among humans) and 10X for interspecies variability (differences between humans and animals). There are ten occupational handler exposure scenarios assessed for mixers, loaders, and applicators applying water dispersible granule:

1) mixing and loading granulars for aerial application (fruit trees and conifers)
2) mixing and loading granulars for airblast application (fruit trees, caneberries, conifers, rough lemon nursery stock and field grown flowers)
3) mixing and loading granulars for groundboom application (cranberries, caneberries, tobacco, conifers, rough lemon nursery stock and field grown flowers)
4) aerial application of liquids
5) application of liquid by air blast sprayer
6) application of liquid by groundboom
7) application of liquid by high pressure handwand (field grown flowers and rough lemon nursery stock)
8) mixing, loading and applying liquids with low pressure handwand (tobacco plant beds and spot treat cranberries)
9) mixing, loading and applying liquids with backpack sprayer (tobacco plant beds and spot treat cranberries)
10) flagging for aerial spray application

The ten occupational scenarios resulted in the following PPE requirements and MOEs:

- At baseline PPE (long pants, long sleeved shirts, shoes and socks): mixing and loading for all airblast and groundboom applications have MOEs above 100, except for rough lemon nursery stock, for which the registrant has requested to voluntarily cancel use.

- At baseline PPE: applying sprays for all aerial and groundboom applications have MOEs above 100; however, aerial application is being prohibited in order to eliminate handler exposure with MOEs below the target of 100.

- Addition of chemical resistant gloves and PF5 respirator brings all mixers, loaders and applicators using low pressure handwands to MOEs of 100 or above.

- Addition of chemical resistant gloves and a PF5 respirator brings all mixers, loaders and applicators using high pressure hand wand applications to an MOE of 120.

- Addition of chemical resistant gloves and a PF10 respirator for all backpack sprayers (cranberry spot treatment) brings the MOE to 90.

- Addition of chemical resistant gloves, double layers, and a PF5 respirator, for all airblast applicators bring the MOEs between 115 to 227, when calculated using the revised maximum rates (see Table 6).

Table 6. Aggregate MOEs for Airblast Application			
Crop	**New Max. App. Rate (lb ai/A) (previous typical rate)**	**MOE w/Baseline PPE**	**MOE w/ Gloves, Double Layers, and PF5 Respirator**
Citrus	6.0	40	115
Apples/Pears	3.5	80	200
Peaches/Cherries	3.42	80	202

Post-Application Occupational Risk

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before workers can safely re-enter. Handler and worker risks were assessed for the inhalation and dermal routes. Currently, all ferbam labels require a REI of 24 hours for all application scenarios.

The Agency has determined that workers may be exposed to ferbam upon entering areas which have been previously treated to perform specific work activities in these areas (e.g., harvesting, pruning, training, and thinning). Five post-application exposure scenarios were assessed for ferbam: low berries, deciduous fruit-trees, cut flowers, Christmas trees and vine and trellis crops. The cut flowers and Christmas trees scenarios will be voluntarily cancelled by the registrant.

The post application exposure and risk were assessed on the day of treatment (day 0), and estimated using the thiram DNT endpoint of 1.4 mg/kg/day. When this thiram endpoint was used along with the typical application rates for ferbam, the MOEs were above 100 (except for grapes, MOE = 85). Using the current maximum application rates, some of the MOEs were below the target of 100 (50 - 250). The typical application rates are most commonly used and reflect data from the National Agriculture Statistics Survey (NASS). The Agency is confident that based on the typical application rates applied, and an REI of 24 hours, workers have adequate protection in treated fields.

Therefore, maximum application rates on the following crops will be lowered to be comparable with typical (reported) rates in order to provide adequate worker protection for post-application activities. Maximum rates on the following crops will be reduced to: 3.5 lb ai/A for apples, pears, and cherries; 3.0 lb ai/A for mangos; and 2.0 lb ai/A for grapes. For a detailed discussion of the post-application scenarios, please refer to the Memo entitled Addendum to the Risk Assessment and Reregistration Eligibility Decision (RED) for Ferbam dated 9/26/05 by R. Daiss.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment for ferbam is presented below. Ferbam has the following registered uses which result in environmental exposures: groundboom airblast, and aerial application to citrus, pome fruits, and stone fruits. In addition, low pressure hand wand applications to cranberries have potential for environmental exposures. The registrant has

requested voluntary cancellation on several crops, will decrease application rates, and will delete aerial application from their labels, thereby limiting total potential environmental exposures. More detailed information about the environmental risk from the use of ferbam can be found in the "EFED Error Correction for the RED Chapter for Ferbam," dated 2/23/05. The complete environmental risk assessment may be accessed in the OPP Public Docket (OPP-2004-0337) and on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

The environmental fate database is sufficient to characterize the environmental exposure associated with ferbam use. However, EPA does intend to issue a DCI as part of this RED to require submission of additional data for the parent compound to address areas of uncertainty. Studies on aquatic invertebrates and freshwater fish will help to refine the environmental risk assessments and provide the Agency with necessary data. These data are expected to confirm the conclusions of this environmental risk assessment.

1. Environmental Fate and Transport

Ferbam is not persistent in the environment because it degrades rapidly via hydrolysis, photodegradation, and aerobic soil metabolism to its major degradate thiram, with half-lives less than or equal to 31 minutes. As thiram is more persistent in soils and water, the environmental fate assessment focused on the levels of thiram in the environment.

2. Ecological Risk Assessment

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

Aquatic Organism Risk

The effects associated with ferbam exposure to aquatic organisms were evaluated based on available data from acute toxicity studies on thiram since thiram is a primary degradate of ferbam in aquatic systems. Based on these studies, thiram is classified as highly toxic to estuarine/marine aquatic invertebrates (LC_{50}<0.1 ppm) and highly toxic to estuarine/marine fish and freshwater invertebrates (LC_{50}=0.21 ppm).

Estuarine and marine aquatic invertebrates are the most susceptible aquatic species to thiram exposure. As the highest application rates of ferbam occur for citrus crops in the Southeastern region, there is potential concern for impact to estuarine and marine invertebrates. In the Northeast, ferbam is applied to cranberries which are grown in coastal systems or close to freshwater river and lake

systems. Spray drift may cause higher concentrations of ferbam and thiram in adjacent bodies of water resulting in a higher risk to aquatic organisms.

For aquatic organisms, the acute risk LOC is 0.5, the acute restricted use LOC is 0.1, and the acute endangered species risk LOC is 0.05. RQs which are greater than the LOC may pose a risk of concern.

Acute Risks

The aquatic organism risk assessment was conducted assuming maximum application rates and residue levels: Freshwater fish RQ values range from 0.15 - 1.14, and RQs for freshwater invertebrates range from 0.03 - 0.22. Estuarine and marine fish RQs range from 0.011- 0.09, where as estuarine and marine invertebrate RQs range from 1.8 -14.3. Endangered species LOCs were exceeded for all crop scenarios for freshwater fish and estuarine/marine invertebrates.

Chronic Risks

No data are available assessing the chronic toxicity of thiram or ferbam to freshwater fish or aquatic invertebrates. As a result, chronic risks of concern cannot be precluded for aquatic organisms. The Agency intends to call in data on freshwater fish and aquatic invertebrates.

For the aquatic assessment, the highest exposure is expected for rough lemon and citrus crops in Florida (which have the highest application rates), resulting in the highest estimated environmental concentrations (EECs) and risks. However, the registrant will not support ferbam use on rough lemon nursery stock, thereby eliminating the potential for this high exposure scenario.

For a more detailed discussion of risk to aquatic animals including a discussion of toxicity data and aquatic modeling, see Section B. Risk Description - Interpretation of Direct Effects of the EFED Error Correction for the RED Chapter for Ferbam dated 2/23/05.

Terrestrial Risk

Terrestrial wildlife exposure estimates are typically calculated for birds and mammals, emphasizing a dietary exposure route for uptake of pesticide active ingredients. For exposure to terrestrial organisms, such as birds and small mammals, pesticide residues on food items are estimated, based on the assumption that organisms are exposed to a single pesticide residue in a given exposure scenario. Maximum residue levels and application rates are assumed for the ELL-FATE model used to conduct the terrestrial assessments.

Ferbam is categorized as slightly toxic to practically non-toxic to birds and practically non-toxic to mammals on an acute basis. Thiram is categorized as slightly toxic to birds and practically non-toxic to mammals. For terrestrial organisms, the acute LOC is 0.5, the acute restricted use LOC is 0.2, and the acute endangered species LOC is 0.1. RQs which exceed the LOC may pose a risk of concern.

The range of values in the terrestrial RQs results from conducting single and multiple applications, as well as the variety of mammals used in the ELL-FATE model. The mammals used in the model ranged in size from 15g to 1000g, resulting in the following RQs:

Acute Risks for Birds

The acute RQs for single applications of thiram equivalents of ferbam range from 0.01 - 1.0. The acute RQs for multiple applications of thiram equivalents of ferbam range from 0.01 - 2.

Acute Risks for Mammals

The acute RQs for single applications of thiram equivalents of ferbam range from <0.01 - 1.5. The acute RQs for multiple applications of thiram equivalents of ferbam range from <0.01 - 2.5.

Chronic Risks for Birds and Mammals

Reproductive studies in birds show that chronic dietary exposure can result in adverse effects for several reproductive parameters, including decreased egg production, viable embryos and hatchling survival and growth (No Observable Adverse Effect Concentration of 9.6 ppm ai). Harmful effects include reproductive toxicity for birds, and decreased body weight for mammals.

Chronic RQs for both mammals and birds exceed the LOC for chronic effects (1.0) for all scenarios. The chronic RQs for birds range from 5 - 400 and for mammals from 1.5 - 137 with single applications. Similarly, with multiple applications the RQs for birds range from 5 - 700 and for mammals from 1.5 - 228.

This chronic assessment was conducted with some conservative assumptions including a default foliar half-life of 35 days. This is likely a substantial overestimate of the persistence of thiram in the environment. In addition, a generic bird or mammal is assumed to eat 100% of its food from the treated area. As a result, it is estimated that young birds and small mammals may consume a toxic dose large enough to cause adverse effects due to their lower body weights and higher energy requirements. For more information on the risk to terrestrial animals refer to Section B. Risk Description - Interpretation of Direct Effects of the EFED Error Correction for the RED Chapter for Ferbam dated 2/23/05.

Ecological Incidents

The Agency has received no reports of ferbam ecological incidents.

Risk to Endangered Species

The Agency's preliminary risk assessment for endangered species indicates that RQs exceed endangered species LOCs for all scenarios assessed. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

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

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

Based on its evaluation of ferbam, the Agency has determined that ferbam 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 ferbam. If all changes outlined in this document are incorporated into the product labels, then all current risks for ferbam will be adequately mitigated for the purposes of this determination under FIFRA. Once the Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in section D.1. Endangered Species Considerations, below.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for ferbam. During the public comment period on the risk assessments, which closed on June 27, 2005, the Agency received three comments from two private citizens, and Taminco/VJP Consulting. These comments in their entirety are available in the public docket (OPP-2004-0337) at http://www.regulations.gov. A detailed Response to Comments document is available in the public docket as well.

The RED and technical supporting documents for ferbam are available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket identification (ID) number OPP-2004-0337. The public may access EPA Dockets at http://www.epa.gov/edockets. In

addition, the ferbam RED may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Food Quality Protection Act Findings

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food and water sources) exposure to ferbam is within its own "risk cup." An aggregate assessment was conducted for exposures through food and drinking water. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for ferbam meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and water. The FQPA Safety Factor has been reduced to 1X for ferbam because acceptable developmental and reproduction studies have been submitted and reviewed, and there is a low concern and no residual uncertainties for pre- and postnatal toxicity or exposure. In addition, there are no concerns for *in utero* exposure.

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 data on ferbam indicated that there was no toxicologically significant evidence of endocrine disruption effects. However, it has been found in chronic exposure studies that thiram produces adverse reproductive effects in birds, including decreased egg production, viable embryos, and hatchling survival and growth. These data suggest that future testing with appropriate screening and/or testing protocols, could better characterize effects related to endocrine disruption.

3. Cumulative Risks

Risks summarized in this document are those that result only from the use of ferbam. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for ferbam.

4. Tolerance Reassessment Summary

The existing tolerances for residues of ferbam (ferric dimethyldithiocarbamate) are established under 40 CFR §180.406. The crops for which the Agency plans to revoke tolerances include apricots, asparagus, beans, blueberries, blackberries, youngberries, caneberries, cabbage, cucumbers, lettuce, papaya, peas, squash, and tomatoes (see Table 7).

Table 7. Tolerance Reassessment for Ferbam

Commodity	Current Tolerance (as ppm zineb)	Reassessed Tolerance (as ppm CS_2.)	Comment
Tolerances Established Under 40 CFR §180.114			
Apple	7	TBD [a]	Use supported by registrant
Apricot	7	Revoke	Cancelled
Asparagus	7	Revoke	Cancelled
Bean	7	Revoke	Cancelled
Blackberry	7	Revoke	Cancelled
Blueberry (huckleberry)	7	Revoke	Cancelled
Boysenberry	7	Revoke	Cancelled
Cabbage	7	Revoke	Cancelled
Cherry	7	TBD[a]	IR-4 intends to support this use.
Cranberry	7	4	IR-4 intends to support this use.
Cucumber	7	Revoke	Cancelled
Dewberry	7	Revoke	Cancelled
Fruit, Citrus	7	4	Use supported by registrant
Grape	7	TBD[a]	IR-4 intends to support this use.
Guava	7	Revoke	Cancelled
Lettuce	7	Revoke	Cancelled
Loganberry	7	Revoke	Cancelled

Table 7. Tolerance Reassessment for Ferbam			
Commodity	Current Tolerance (as ppm zineb)	Reassessed Tolerance (as ppm CS_2.)	Comment
Mango	7	TBD[a]	Use supported by registrant (SLN)
Nectarines	7	TBD[a]	Use supported by registrant
Papaya	7	Revoke	Cancelled
Peach	7	TBD[a]	Use supported by registrant
Pear	7	TBD[a]	Use supported by registrant
Pea	7	Revoke	Cancelled
Raspberry	7	Revoke	Cancelled
Squash	7	Revoke	Cancelled
Tomato	7	Revoke	Cancelled
Youngberry	7	Revoke	Cancelled
[a]TBD = To be determined. Although additional data are required to confirm the existing tolerances in or on the following commodities, the Agency has no dietary or drinking water concerns associated with these tolerances and considers them reassessed: peaches; nectarines; pears; mangos; grapes; cherries; and apples.			

D. Regulatory Rationale

The Agency has determined that ferbam 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.

The following is a summary of the rationale for managing risks associated with the use of ferbam. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document. Due to risk exceedances for aquatic invertebrates and terrestrial organisms, ferbam labels must be amended to prohibit aerial application and limit total applications on most crops to three per year. Likewise, rate reductions on pome fruits and citrus will reduce overall exposure to ferbam. In addition, to decrease worker risk, scenario-specific PPE is required.

1. Endangered Species Considerations

From the screening level assessment, RQs exceeded the LOCs for endangered species for many of the representative exposure scenarios considered. All chronic RQs for all uses exceeded LOCs for endangered birds and mammals under both single applications (RQs for birds ranged from 5 to 400 and for mammals they ranged from 1.5 to 137) and multiple applications (RQs for birds ranged from 5 to 700 and for mammals they ranged from 1.5 to 228). Since there were risks to endangered birds and fish, risk to endangered reptiles and amphibians is also possible, should exposure actually occur.

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

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

2. Mitigation

There were some occupational and ecological risks of concern identified for ferbam. To be eligible for reregistration, the following mitigation measures are necessary:

Ecological and Occupational Mitigation:

- *Delete aerial application for all uses.* The Agency requires that aerial application be cancelled to decrease risk to aquatic organisms from spray drift. In addition, the deletion of aerial application will eliminate handler exposure which had MOEs below the target of 100 for mixing and loading.

- *Decrease single maximum application rate for some uses.* The Agency requires that single maximum application rates be decreased to 3.5 lb ai/A for apples, pears and cherries; 3.0 lb ai/A for mangos; and 2.0 lb ai/A for grapes. These decreased rates will result in post application MOEs near or above the target MOE of 100, and lowered exposures to non-target animals.

Ecological:

- *Limit the number of ferbam applications to a maximum of three per year for all remaining uses except SLNs.* Current ferbam labels do not limit the number of applications per year, and this mitigation measure will serve to decrease the potential environmental loading and resulting residues of ferbam in surrounding water bodies.

- *Decrease single maximum application rate for citrus.* The Agency requires that single maximum application rates be decreased to 6.0 lb ai/A for all remaining citrus uses. This decreased rate will result in lowered exposures to non-target animals.

- *Voluntarily cancel ferbam use on rough lemon nursery stock, conifers, and flowering plants.* The cancellations will eliminate uses with high application rates and reduce overall ferbam exposure to non-target organisms.

Occupational:

- *Delete high pressure handwand application for all uses.* The registrant is voluntarily cancelling use on flowers (ornamentals) and rough lemon nursery stock which were the only crops with high pressure handwand application. This deletion eliminates a handler scenario that had MOEs below the target of 100 with baseline PPE.

- *PF5 respirator, double layers, and chemical resistant gloves are required for all airblast applications.* Use of a PF5 respirator, double layers, and chemical resistant gloves brings all MOEs for airblast above the target of 100.

3. Significance of Ferbam Use

There are many advantages to the use of ferbam as a fungicide. EPA has received comments supporting the continued use of ferbam to control fungal outbreaks on a variety of crops. USDA, private citizens, and grower organizations have expressed their need for the use of ferbam as a rotational partner with other fungicides, and a part of an efficacious pest management program.

The Agency is committed to long-term pest resistance management strategies, and an important pesticide resistance management strategy is to avoid the repeated use of pesticides with the same or similar mode of action. Ferbam has virtually no resistance issues, and there are no human health risks of concern. Ferbam provides an important fungicidal niche use for citrus, mangos, peaches, nectarines, and cranberries.

Ferbam is effective on citrus, by controlling the onset of postbloom fruit drop (PFD), and scab. Approximately 45,000 lb ai are applied to citrus crops in Florida. Thiophanate-methyl is one of the alternatives for PFD, but it is permitted only as a section 18 for citrus use, and thus may not always be available. To manage scab, ferbam and the strobilurins are both effective as rotational partners. Ferbam is also a good rotational partner with the coppers and thiophanate-methyl.

In New England and New Jersey, ferbam is effective for the treatment of leaf curl in peaches and nectarines. In addition, ferbam is effective for treating anthracnose on mangos in Florida.

On cranberries, ferbam is used to treat fairy ring, the associated vine dieback, and fruit rot. The higher ferbam application rate allowed by the SLN registrations in New Jersey and Massachusetts is efficacious for spot treatment of fairy ring outbreaks. The other alternatives for control of fruit rot include: azoxystrobin, chlorothalonil, the EBDC's mancozeb and maneb, as well as various copper fungicides. Ferbam is effective for treatment of cranberries for the following reasons:

- low phytotoxicity for in-bloom applications,
- reasonable antifungal activity,
- no inhibition of the development of anthocyanins, and
- low risk for resistance development and complements azoxystrobin in this way.

The use of thiram on apples has been voluntarily cancelled as a result of the Thiram RED (September 2004), and ferbam serves as a viable substitute to control fungal outbreaks in orchards. Ferbam is efficacious in the control of apple scab, black rot, bitter rot, sooty blotch, fly speck, and Brook's spot. Thus, ferbam provides an alternative fungicide to decrease the potential for resistance problems in apples.

4. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is proposing mitigation measures for aerial applications that should be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate.

From its assessment of ferbam, as summarized in this document, the Agency concludes that no additional drift mitigation measures are needed for ferbam. The deletion of aerial application from the ferbam labels will reduce the amount of drift from crops. In the future, ferbam 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 ferbam is eligible for reregistration provided that product-specific data are submitted and the mitigation measures stated in this document are included in upcoming label submissions. In the near future, the Agency intends to issue Data Call-In (DCIs) notices

requiring product specific data and generic confirmatory (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Listed below is the additional generic data that the Agency intends to require.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of ferbam for the above eligible uses has been reviewed and determined to be substantially complete based on bridging to thiram data. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED (see Table 8).

Table 8. Data Requirements for the Ferbam Reregistration Eligibility Decision

Guideline Study Name	New OPPTS Guideline No:	Old Guideline No:
Crop Field Trials (Citrus Food Groups, Pome Fruits Groups, Stone Fruits Group)	860.15	171-4K
Storage Stability	885.24	153A-9
Field Accumulation in Rotational Crops Study	860.19	165-2
Freshwater Fish Early Life-Stage	850.13	72-4
Aquatic Invertebrate Life-Cycle	850.135	72-4B
Freshwater Fish Full Life-Cycle	850.15	72-5

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. Based on the review of the available data, the EPA has determined that ferbam is eligible for a 12 hour REI on all product labels except for those containing other active ingredients with more restrictive REIs.

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. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. 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.

2. Labeling for End-Use Products

In order for ferbam to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measures outlined in the Mitigation section, which include deleting aerial application, decreasing the maximum number of applications per year, and decreasing the maximum single application rates on pome fruits and citrus. Table 9 describes how language on the labels should be amended.

Table 9. Summary of Labeling Changes for Ferbam		
Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into a fungicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]" End-use products must be amended to cancel use on rough lemon nursery stock, ornamentals, and conifers. In addition, end-use labels to prohibit aerial application.	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products of any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA."	Precautionary Statements
End-Use Products Intended for Occupational Use		

PPE Requirements Established by the RED for Dry Flowable Formulation	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators and other handlers must wear: -long sleeved shirts, -long pants, -shoes and socks, -chemical resistant gloves and PF5 respirator when loading and applying with low pressure handwand, -chemical resistant gloves and a PF10 respirator when loading and applying with a backpack sprayer, -applicators must wear chemical resistant gloves, double layers, and a PF5 respirator when applying with airblast applicator."	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." "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. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Environmental Hazards	This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from treated areas.	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval for products with directions for use within 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 Entry Personal Protective Equipment for products with directions for use 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 plants, soil, or water, is: * coveralls, * shoes plus socks and, * chemical-resistant gloves made of any waterproof material."	Directions for Use, Under Agricultural Use Requirements box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box

Other Application Restrictions (Note: The maximum allowable application rate and maximum allowable rate per year must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	The following risk mitigation measures must be made on the labels that contain these use-patterns. Remove all directions for use for rough lemon nursery stock, conifers, and flowering plants Aerial application is prohibited. **Apples and Pears:** Add: "Maximum of three ferbam applications per year. Maximum single application rate of 3.5 lb ai/A." **Citrus:** Delete:` All directions for use on rough lemon nursery stock Add: "Maximum of three ferbam applications per year. Maximum single application rate of 6 lb ai/A." **Cherries:** Add: "Maximum of three applications per year. Maximum single application rate of 3.5 lb ai/A."	

	Nectarines and Peaches: Add: "Maximum of three ferbam applications per year Maximum single application rate of 3.4 lb ai/A" **Cranberries:** Add: "For groundboom: maximum single application rate of 4.56 lb ai/A Maximum of 5 groundboom applications per year. For spot treatment: apply 6.84 lb ai/100 gallons of water and apply 0.76 gallon of this mixture to a 1 sq. foot area = 2264 lb ai/A Maximum of 1 spot treatment application per year" **Mangos:** Add: "Maximum single application rate of 3.0 lb ai/A Maximum of 16 applications per year." **Grapes:** Add: "Maximum single application rate of 2.0 lb ai/A Maximum of 3 applications per year."	

Spray Drift Language for Products Applied Outdoors	"SPRAY DRIFT MANAGEMENT" This chemical can contaminate surface water through spray drift. A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground and airblast) can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product Do not allow this material to drift onto neighboring crops or non-crop areas or use in a manner or at a time other than in accordance with label directions because animal, plant or crop injury, illegal residues or other undesirable results may occur **Wind Speed** " Do not apply at wind speeds greater than 15 mph." **Temperature Inversions** "Do not make applications into areas of temperature inversion or stable atmospheric conditions" For ground boom applications • nozzle height no more than 10 feet above the ground or crop canopy • wind speed is 10 mph or less at the application site and, • medium or coarser spray according to ASAE 572 definition for standard nozzles	

VI. Appendices

Appendix A. Food/Feed Use Patterns for Ferbam				
Site Application Type Application Equipment	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications	Minimum Retreatment Interval	Use Limitations
Apples Airblast	3.5	3	7	The best use is in the cover sprays. Do not apply late season where unsightly residues may affect the fresh fruit finish of light-skinned apple varieties. **Do not** apply within 7 days of harvest.
Pears Airblast	3.5	3	7	*For Scab*: Make applications at pink, calyx, first and second cover sprays, and 1 lb. in summer sprays. Do not apply late season where unsightly residues may affect the fresh fruit finish of light-skinned pear varieties.
				For Leaf Blight: Make applications in summer cover sprays. Do not apply late season where unsightly residues may affect the fresh fruit finish of light-skinned pear varieties. **Do not** apply within 7 days of harvest.

Cherries	3.5	3	7	Apply from petal fall through cover sprays. May also use 1 lb of Ferbam Granuflo plus 3 lbs of wettable sulfur in petal fall and cover sprays. To aid in the control of Leaf Spot, apply 1.5 lbs per 100 gallons of water immediately prior to harvest but prior to leaf drop. Applications may be made up to the day of harvest.
Mangos	3.0	16	7	Refer to Special Local Need label
Grapes Ground	2.0	3	7	Do not apply in late season sprays where unsightly residues may affect the fresh fruit finish of light-skinned grape varieties. Taminco recommends the use of Ziram Granuflo (East of the Rockies) for late-season fresh fruit sprays. Do not make more than 3 applications per season. Do not apply within 7 days of harvest.
Citrus Broadcast foliar application Groundboom	6.0	3	14	*For Anthracnose, Scab, Postbloom Fruit Drop:* Apply during pre-bloom periods and 2/3 petal fall. May be applied in late summer and early fall if a heavy flush of growth appears. May be applied up to the day of harvest.

				For Scab: Apply at 7 to 10 day intervals and after heavy rains during growing periods
Peaches and Nectarines Broadcast foliar application	3.4	3	120	Apply during the dormant period in the fall after leaves drop or in the Spring before buds begin too swell. If Leaf Curl has been severe, make 2 applications, 1 in the Fall and 1 in the Spring during the dormant period. **Do not** apply within 21 days of harvest.
Tobacco Groundboom	4.4	5		Apply at a rate of 3 gallons per 100 square yards when plants are small, increasing to 6 gallons when plants are ready for transplanting. Begin applications when plants are the size of a dime or when Blue Mold is reported in the area, and repeat twice weekly until plants are transplanted.
Cranberries Groundboom Spot Treatment	4.6	5	7	*For Fruit Rots:* Begin applications early in blossoming period and repeat at 2 week intervals for a total of 5 applications. **Do not** apply within 28 days after mid-bloom.

				For Fairy Ring: Treat an area 3 feet beyond the advancing line of dead vines and 2 feet within this line. Apply in the Fall immediately after harvest. **Restriction**: Do not use water from treated cranberry bogs for irrigating other crops.
	Apply 6.84 lb ai/100 gallons of water and apply 0.76 gallon of this mixture to a 1 sq. foot area = 2264 lb ai/A	1	7	For Spot Treatment of Fairy Ring

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Ferbam				
New Guideline Number	**Old Guideline Number**	**Description**	**Use Pattern**	**Citation**
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Oral LD_{50}	AB	00099594 (thiram)
850.2200	71-2	Avian Dietary LC_{50}	AB	00010616, 00010618 (thiram)
850.2300	71-4	Avian Reproduction	AB	45441201(thiram)
850.1075	72-1	Freshwater Fish LC_{50}	AB	00070810 (thiram)
850.1010	72-2	Freshwater Invertebrate Acute LC_{50}	AB	00164662 (thiram)
None	72-3a	Estuarine/Marine Fish LC_{50}	AB	42514401 (thiram)
850.1025	72-3b	Estuarine/Marine Mollusk LC_{50}	AB	42488301 (thiram)
850.1035	72-3c	Estuarine/Marine Shrimp LC_{50}	AB	42488302 (thiram)
850.1300	72-4a	Freshwater Fish Early Life-Stage	AB	DATA GAP
850.1350	72-4b	Aquatic Invertebrate Life-Cycle	AB	DATA GAP
850.1500	72-5	Freshwater Fish Full Life-Cycle	AB	DATA GAP
850.1500	72-2	Aquatic Algal Growth	AB	45441202 (thiram)
850.4400	123-2	Aquatic Plant Growth	AB	45441202 (thiram)
850.3020	141-1	Honey Bee Acute Contact LD_{50}	AB	00003635 (thiram)
TOXICOLOGY				
870.1100	81-1	Acute Oral, Rat	AB	40561501 (ferbam)
870.1200	81-2	Acute Dermal, Rabbit	AB	40561502 (ferbam)
870.1300	81-3	Acute Inhalation, Rat	AB	41508101 (ferbam)

870.2400	81-4	Acute Eye Irritation, Rabbit	AB	40561503 (ferbam)
870.2500	81-5	Acute Dermal Irritation, Rabbit	AB	40561505 (ferbam)
870.2600	81-6	Skin Sensitization, Guinea Pig	AB	40561504 (ferbam)
870.3100	82-1a	90-Day Oral Toxicity CD Rats	AB	00143817 (ferbam)
870.3700	83-3a	Prenatal Developmental in Rats	AB	00143816 (ferbam)
870.3700	83-3a	Prenatal Developmental in Mice	AB	00143816 (ferbam)
870.3800	83-4	Reproduction and Fertility Effects (Rats)	AB	00143816, 00085454 (ferbam)
870.4100a	83-1a	Chronic Toxicity 2 Year (Ex-Wistar Rats)	AB	00083231 (ferbam)
870.4100a	83-1a	Chronic Toxicity 80 Weeks (CD Rats)	AB	00143817 (ferbam)
870.4100b	83-1b	Chronic Toxicity 1 Year, Dogs	AB	00083231 (ferbam)
870.4200	83-2a	Chronic Toxicity, 2 Years (Ex-Wistar Rats)	AB	00083231, 00143817 (ferbam)
870.7485	85-1	Metabolism and Pharmacokinetics (Rats)	AB	Literature Studies[1] (ferbam)
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	AB	44071801 (ferbam)
835.2240	161-2	Photodegradation in Water	AB	43999801 (ferbam) 40444704 (thiram)

[1]The data requirement has been satisfied by open literature sources and there is no additional data required at this time.

835.2410	161-3	Photodegradation in Soil	AB	43999802 (ferbam)
835.4100	162-1	Aerobic Soil Metabolism	AB	44368901 (ferbam) 43734901 (thiram)
835.4200	162-2	Anaerobic Soil Metabolism	AB	44565303 (ferbam)
835.4400	162-3	Anaerobic Aquatic Metabolism	AB	43628501, 45243401 (thiram)
835.4300	162-4	Aerobic Aquatic Metabolism	AB	45243401 (thiram)
835.1240 835.1230	163-1	Leaching Adsorption/Desorption	AB	43787501 (thiram) supplemental
835.6100	164-1	Terrestrial Field Dissipation	AB	44724502 (thiram)
840.1100	201-1	Droplet Size Spectrum	AB	41336801 (thiram)
OCCUPATIONAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	AB	43282101, 43282102 (ziram)
RESIDUE CHEMISTRY				
860.1200	171-3	Directions for Use	AB	refer to appendix A
860.1300	171-4A	Nature of the Residue-Plants	AB	4350001, 43562201 44992501 (ferbam and ziram)
860.1300	171-4B	Nature of the Residue-Livestock	AB	43803301, 42839201, 42677501 (ferbam, thiram and ziram)
860.1340	171-4C	Residue Analytical Methods-Plant and Animal commodities	AB	41229801, 41223901 (ferbam)
860.1380	171-4E	Storage Stability Data--Plant Processed commodities and animal commodities	AB	43949701, 44565304, 42677501 (ferbam)

860.1500	171-4K	Crop Field Trials (citrus food groups, pome fruit groups, and stone fruits groups)	AB	DATA GAP, 44565301, 44565302, 44565303, 44565304, 45146101 (ferbam)
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed	AB	44565304 (ferbam)
860.1900	165-2	Field Accumulation in Rotational Crops Study	AB	DATA GAP
885.2400	153A-9	Storage Stability	AB	DATA GAP

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of August 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on June 16, 1999.

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

www.epa.gov/pesticides/reregistration

These documents include:

HED Documents:

I. Revised Ferbam HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document. April 19, 2005.

II. Ferbam: Addendum to the Risk Assessment and Recommendations for the Reregistration Eligibility Decision (RED) for Ferbam. October 11, 2005.

III. Revised Ferbam Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision. March 3, 2005

IV. Thiram: Nature of the Residue in Animals - Goat Metabolism Study. October 5, 2004

V. Ferbam: Magnitude of the Residue- Citrus Field Trials and Orange Processing Study. October 5, 2004.

VI. Occupational Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED) for Ferbam. December 30, 2004

VII. Revised Ferbam Residue Chemistry Considerations for Reregistration Eligibility Decision. March 3, 2005.

VIII. Ferbam Report of the Health Effects Division (HED) Risk Assessment Review Committee (RARC). August 5, 2004.

EFED Documents:

I. EFED Error Correction for the RED Chapter of Ferbam. February 23, 2005.

II. Tier II Estimated Drinking Water Concentrations of Ferbam August 19, 2004.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Interim Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D.

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

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

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

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

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

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

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

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

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

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

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

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

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00010616 Fink, R.; Reno, F. (1973) Final Report: Eight-day Dietary LC50– Bobwhite Quail: Ferbam: Project No. 104-172. (Unpublished study received Jun11, 1973 under 279-388; prepared by Environmental Sciences Corp., submitted by FMC Corp., Philadelphia, PA; CDL:008720-A)

00010618 Fink, R.; Reno, F. (1973) Final Report: Eight-day Dietary LC50– Mallard Ducks: Ferbam: Project No. 104-173. (Unpublished study received Jul11, 1973 under unknown admin. no; prepared by Environmental Sciences Corp., submitted by FMC Corp., Philadelphia, PA; CDL:130715-A)

40550902 Selman, F.; Moezpoor, E. (1988) Ferbam Peach Terrestrial Field Dissipation: Preliminary Report No. 35506. Unpublished study prepared by Analytical Bio-chemistry Laboratories, Inc. 65 p.

40561501 Reijnders, J. (1987) Evaluation of the Acute Oral Toxicity of Ferbam Technical in the Rat: Laboratory Project ID NOTOX 0740/930. Unpublished study prepared by Notox C. V., Netherlands. 11 p.

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40561503 Weterings, P.; Daamen, P. (1987) Assessment of Primary Eye Irritation/Corrosion by Ferbam Technical in the Rabbit: Laboratory Project ID NOTOX 0740/933. Unpublished study prepared by Notox C. V., Netherlands. 13 p.

40561504 Weterings, P.; Daamen, P. (1987) Assessment of the Skin Sensitization Potential of Ferbam Technical in the Guinea-pig (Split Adjuvant Test): Laboratory Project ID NOTOX 0740/934. Unpublished study prepared by Notox C. V., Netherlands. 13 p.

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40603401 Selman, F.; Moezpoor, E. (1988?) Ferbam Apple Terrestrial Field Dissipation: Preliminary Report No. 35507. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 138 p.

41223901 Orius Associates Inc. (1989) Ferbam: Magnitude of the Residue in or on Peaches Treated by Ground or Aerial Equipment in California, Georgia, Michigan, North Carolina, Oklahoma, Pennsylvania, and Washington, 1988: Project ID 30889. Unpublished study. 942 p.

41508101 Hardy, C. ; Jackson, G. (1990) Ferbam Technical: Acute Inhalation Toxicity in Rats--4-Hour Exposure: Lab Project Number: UCB 285/ 88179. Unpublished study prepared by Huntingdon Research Centre. 45 p.

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43949701 Koch, D. (1996) Frozen Storage Stability of Ferbam and Ziram in Apples: Final Report: Lab Project Number: 42656: UCB 1995-70. Unpublished study prepared by ABC Laboratories, Inc. 53 p.

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44992501 Kang, H.; Robinson, R. (1999) Metabolic Fate and Distribution of (carbon-14) Thiram in Apple: Lab Project Number: R369801: XBL98041: RPT00519. Unpublished study prepared by Xenobiotic Labs, Inc. 427 p. {OPPTS 860.1300}

43999801 Nixon, W. (1996) Aqueous Photolysis of (Carbon 14) Ferbam in Artificial Light: Lab Project Number: 1002: 1884. Unpublished study prepared by PTRL East, Inc. 123 p.

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44368901 Nixon, W.; Atkins, R.; Coody, P. (1997) Aerobic Soil Metabolism of (carbon 14)Ferbam: (Final Report): Lab Project Number: 1004: 1903: 95047. Unpublished study prepared by PTRL East, Inc. 110 p.

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45335601 Biehn, W. (2001) Ferbam: Freezer Storage Stability in Macerated (Ground) Cranberries: Lab Project Number: A4092: A4092. AA-NYR13. Unpublished study prepared by Cornell University and Rutgers University. 64 p. {OPPTS 860.1500}

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43999801 Nixon, W. (1996) Aqueous Photolysis of (Carbon 14) Ferbam in Artificial Light: Lab Project Number: 1002: 1884. Unpublished study prepared by PTRL East, Inc. 123 p.

43999802 Nixon, W. (1996) Soil Surface Photolysis of (Carbon 14) Ferbam in Artificial Light: Lab Project Number: 1003: 1883. Unpublished study prepared by PTRL East, Inc. 100 p.

44368901 Nixon, W.; Atkins, R.; Coody, P. (1997) Aerobic Soil Metabolism of (carbon 14)Ferbam: (Final Report): Lab Project Number: 1004: 1903: 95047. Unpublished study prepared by PTRL East, Inc. 110 p.

THIRAM

00153548 Thouin, M. (1985) Evaluation of the Acute Oral Toxicity of TMTD Technical in the Rat: Study No. 0174/238. Unpublished study prepared by Notox v.o.f Hambakenwetering 31. 19 p.

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43787501 Morgenroth, U. (1995) Adsorption/Desorption of (carbon 14)- Thiram on Four Soils: Lab Project Number: 354780. Unpublished study prepared by RCC Umweltchemie AG. 80 p. THIRAM

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45441201 Gallagher, S.; Martin, K.; Beavers, J. (2001) Thiram Technical: A Reproduction Study with the Mallard: Final Report: Lab Project Number: 357-107. Unpublished study prepared by Wildlife International, Ltd. 143 p.

45441202 Sutherland, C.; Kendall, T.; Krueger, H. (2001) Thiram Technical: A 7-Day Toxicity Test with Duckweed (Lemna gibba G3): Final Report: Lab Project Number: 357A-101. Unpublished study prepared by Wildlife International. Ltd. 79 p. {OPPTS 850.4400}

45714101 Shepler, K.; Runes, H. (2002) Hydrolysis of (Carbon 14) Thiram at pH 5, 7, and 9: Lab Project Number: 1041W. Unpublished study prepared by PTRL West, Inc. 110 p.

45724501 Shepler, K.; Runes, H. (2002) Photodegradation of (Carbon 14) Thiram in/on Soil by Artificial Light: Lab Project Number: 1043W: 1043W-1: 1042W-004. Unpublished study prepared by PTRL West, Inc. 115 p.

43734901 Morgenroth, U.; Mueller-Kallert, H. (1995) (Carbon 14)-Thiram: Degradation and Metabolism in One Soil Incubated Under Aerobic Conditions: Lab Project Number: 326182. Unpublished study prepared by RCC Umweltchemie Ag. 114 p.

45243401 Wyss-Benz, M. (1992) Degradation and Metabolism of Thiram in Aquatic Systems (Amended Report): Lab Project Number: 303456. Unpublished study prepared by RCC Umweltchemie Ag. 156 p.

43628501 Wyss-Benz, M. (1995) (Carbon 14)-Thiram: Degradation and Metabolism in an Anaerobic Aquatic System: Revised Report: Lab Project Number: 329635. Unpublished study prepared by RCC Umweltchemie AG. 110 p.

43787501 Morgenroth, U. (1995) Adsorption/Desorption of (carbon 14)- Thiram on Four Soils: Lab Project Number: 354780. Unpublished study prepared by RCC Umweltchemie AG. 80 p.

44724501 Dykeman, R. (1998) Determination of the Dissipation of Residues of Thiram in

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ZIRAM

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42839201 Bodden, R. (1993) Nature of the Residue in Lactating Goats: Ziram: Final Report: Lab Project Number: HLA 6225-101. Unpublished study prepared by Hazleton Labs America, Inc. 103 p.

43283101 Meikle, S. (1993) Dislodgeable Foliar Residues of Ziram Granuflo Fungicide Applied to Apples in New York, 1990: Lab Project Number: 30488: ML90-0178-ZTF: 46-ZIR/91089. Unpublished study prepared by Orius Associates, Inc.; Morse Labs; and ACDS, Inc. 169 p.

43282102 Meikle, S. (1993) Dislodgeable Foliar Residues of Ziram Granuflo Fungicide Applied to Apples in California, 1990: Lab Project Number: 30488: ML90-0178-ZTF: 46-ZIR/91026. Unpublished study prepared by Orius Associates, Inc.; Morse Labs; and Research for Hire. 182 p.

43282503 Meikle, S. (1993) Ziram: Magnitude of the Residue in or on Peaches Treated by Ground and Aerial Equipment in Georgia, 1990: Addendum: Lab Project Number: 30488: ML90/0176/ZTF: 27/ZIR/ 92005. Unpublished study prepared by Orius Associates Inc., Morse Lab., Georgia Agri-Scientific. 176 p.

43500001 Wyss-Benz, M. (1994) (Carbon 14)-Ziram Plant Metabolism Study in Field Grown Apple: Lab Project Number: 350673. Unpublished study prepared by RCC UMWELTCHEMIE AG. 129 p.

43985801 Kim-Kang, H. (1996) Aerobic Soil Metabolism of (carbon 14)- Ziram: Lab Project Number: XBL 94072: RPT00225. Unpublished study prepared by XenoBiotic Labs, Inc. 180 p.

44097701 Kim-Kang, H. (1996) Aqueous Photolysis of (carbon 14)-Ziram: Lab Project Number: XBL94073: RPT00223: IDC 433102. Unpublished study prepared by XenoBiotic Labs, Inc. 245 p.

44228401 Reynolds, J. (1997) Photolysis of (carbon 14) Ziram on Soil: (Final Report): Lab Project Number: 96001: RPT00296: XBL 96001. Unpublished study prepared by XenoBiotic Laboratories, Inc. 179 p.

43985801 Kim-Kang, H. (1996) Aerobic Soil Metabolism of (carbon 14)- Ziram: Lab Project Number: XBL 94072: RPT00225. Unpublished study prepared by XenoBiotic Labs, Inc. 180 p.

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43873501 Spare, W. (1995) Adsorption/Desorption of (carbon 14)-Ziram: Lab Project Number: 2526: IDC 433102: 94072. Unpublished study prepared by Agrisearch Inc. 162 p.

44548301 Novak, R.; Binari, L. (1998) Terrestrial Field Dissipation of Ziram 76 DF Fungicide in North Carolina: Final Report: Lab Project Number: F96-7204: GR96255: 96-0030. Unpublished study prepared by Grayson Research, Ltd., EN-CAS Analytical Laboratories, and NPC, Inc. 428 p.

44548302 Novak, R.; Binari, L. (1998) Terrestrial Field Dissipation of Ziram 76 DF Fungicide in California: Final Report: Lab Project Number: F96-7203: R319601: ML96-0606-ZTF. Unpublished study prepared by Research for Hire, Morse Laboratories, Inc., and NPC, Inc. 401 p.

45002501 Castro, L. (1999) Dissipation of Dislodgeable Residues of Ziram 76DF from Apple Leaves: Lab Project Number: KP-98-09. Unpublished study prepared by Elf Atochem North America, Inc. 168 p. {OPPTS 875.2100}

45112501 Castro, L. (2000) Dissipation of Dislodgeable Residues of Ziram 76DF from Grape Leaves: Lab Project Number: KP-98-10: 10A-98: 10B-98. Unpublished

study prepared by Elf Atochem North America, Inc. 157 p. {OPPTS 875.2100}

Appendix E. Generic Data Call-In

See attached table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix F. Product Specific Data Call-In

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under a separate cover.

Appendix G. EPA's Batching of Ferbam 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 ferbam 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. Not with-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

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

Four products were found which contain ferbam as the active ingredient. These products have not been placed into a batch group based on the active and inert ingredients and type of formulation.

Batching Instructions:

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

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

No Batch	EPA Reg. No.	Percent Active Ingredient
	5481-256	11.3
	5481-268	76.0
	8660-68	76.0
	45728-7	76.0

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

Taminco
1950 Lake Park Drive
Smyrna, GA 30080

VJP Consulting, Inc
21320 Sweet Clover Place
Ashburn, VA 21047

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

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

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

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

Instructions

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

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

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

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

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

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

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

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

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

- Date of receipt;
- EPA identifying number; and
- 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.