UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF
PESTICIDES PROGRAMS

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the pesticide ziram. Based on EPA's review, the Agency has identified risk mitigation measures that are necessary to address the human health and ecological risks associated with the current uses of ziram. The EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of ziram and its associated human health and environmental risk assessment documents. The enclosed " Reregistration Eligibility Decision for Ziram," which was approved on September 29, 2003, contains the Agency's decision on ziram.

A Notice of Availability for this Reregistration Eligibility Decision (RED) for ziram is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460-0001, Telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet. See http:www.epa.gov/pesticides/reregistration.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA)**,** the Agency is undertaking a special effort to maintain open public dockets on pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. The human health and environmental risk assessments were placed in the public docket and an invitation for public comment was announced in the *Federal Register* on March 27, 2002. In addition, a closure conference call was held on September 25, 2003 during which the Agency presented a summary of the risk assessments and the results of the risk management decision for the registrants, USDA, and other stakeholders.

Please note that the ziram risk assessment and the attached RED concern only this particular chemical. Although ziram belongs to the dithiocarbamate group of fungicides which have neuropathy as a common toxic effect, EPA has concluded that the neuropathy induced by the dithiocarbamates can not be linked to a common mechanism of toxicity 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. Therefore, for the purposes of this risk assessment, the Agency has assumed that ziram does not share a common mechanism of toxicity with any other chemicals.

This document contains a draft copy of the generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that a final DCI, with all pertinent instructions, is being sent to all applicable registrants under separate cover.

In this RED, the Agency has determined that ziram will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of ziram may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this RED. Sections IV and V of this RED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this RED.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by ziram. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the proposed label changes necessary for reregistration, please contact the Chemical Review Manager, Stephanie Plummer, at (703)305-0076. For questions about product reregistration and/or the product DCI that accompanies this document, please contact Jane Mitchell at (703)308-8061.

Betty Shackleford, Acting Director
Special Review and
Reregistration Division

Attachments

REREGISTRATION ELIGIBILITY DECISION

for

ZIRAM

PC Code: 034805

Case: 2180

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Glossary of Terms and Abbreviations

AD	Antimicrobial Division of OPP
a.i.	Active Ingredient
BEAD	Biological and Economic Analysis Division of OPP
BPPD	Biopesticides and Pollution Prevention Division of OPP
aPAD	Acute Population Adjusted Dose
CAS	Chemical Abstracts Service
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSF II	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DF	Dry Flowable Formulation
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level
DWLOC	Drinking Water Level of Comparison
EBDC	Ethylenebisdithiocarbamate
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EFED	Environmental Fate and Effects Division of OPP
e.g.	*Lat*. Exampli gratia (for example)
EIIS	Ecological Incident Information System
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FATE	FIFRA Avian Terrestrial Exposure Model
FC	Flowable Concentrate Formulation
FDA	Food and Drug Administration
FEAD	Field and External Affairs Division of OPP
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
FWS	US Fish and Wildlife Service
G	Granular Formulation
GENEEC	Generic Estimated Environmental Concentration; a Tier I Model
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory
HAFT	Highest Average Field Trial
HED	Health Effects Division of OPP
HDT	Highest Dose Tested
HIARC	Hazard Identification Assessment Review Committee
IDS	Incident Data System of OPP
i.e.	*Lat*. Id est (that is)
IRSD	Information Resources and Services Division of OPP
LC_{50}	Median Lethal Concentration
LD_{50}	Median Lethal Dose
LEL	Lowest Effect Level

LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOQ	Level of Quantitation
MARC	Metabolism Assessment Review Committee
MATC	Maximum Acceptable Toxicant Concentration
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal (MCLG)
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number)
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NMFS	National Marine Fisheries Service
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NTPN	National Pesticide Telecommunication Network
OPP	Office of Pesticide Programs in EPA
OPPTS	Office of Prevention, Pesticides and Toxic Substances in EPA
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PCC	Poison Control Center
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Database
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PR	Pesticide Registration Notice
PRZM/EXAMS	Pesticide Root Zone Model/Exposure Analysis Modeling System, a Tier Computer Model
Q_1*	Carcinogenic Potential of a Compound
RAC	Raw Agriculture Commodity
RD	Registration Division of OPP
RED	Reregistration Eligibility Decision
REI	Re-entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Screening Concentrations In Ground Water, a Tier I Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
SRRD	Special Review and Reregistration Division of OPP

TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
TRAC	Tolerance Reassessment Review Committee
TRR	Total Radioactive Residue
UF	Uncertainty Factor
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WDG	Water Dispensable Granule Formulation
WHO	World Health Organization
WP	Wettable Powder Formulation
WPS	Worker Protection Standard

Executive Summary

The Agency has completed its human health and ecological risk assessments and is issuing its risk management decisions for ziram. The revised risk assessments are based on a review of the required target data base supporting the use patterns of currently registered products and additional information received. After considering the risks identified in the revised risk assessment and comments and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of ziram that pose risks of concern. The decision is discussed fully in this document.

Ziram [Zinc bis(dimethyldithiocarbamate)] is a broad spectrum fungicide used on a variety of crops such as stone fruits, pome fruits, nut crops, vegetables and commercially grown ornamentals. Ziram was first registered in 1968. Approximately 2 million pounds of ziram are used annually. The crops that have the highest percent crop treated are pears, almonds, apricots, and nectarines. Ziram is also registered for use as an industrial preservative in exterior latex paints, adhesives, caulking and sealants. A small quantity of ziram is also formulated into a rabbit repellant to be used by home owners.

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.” Ziram 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. While additional evaluation of possible cumulative effects of ziram and other substances that may have a common mechanism of toxicity is necessary, for the purposes of this reregistration determination, EPA has assumed that ziram does not share a common mechanism of toxicity with other pesticides.

Overall Risk Summary

Dietary and drinking water risks from ziram are below the Agency’s level of concern. There are residential risks to painters, but no assessed residential risk to children or adults from residential uses of ziram as a preservative in paint or as a rabbit repellant for ornamentals.

In an early evaluation for carcinogenicity, the Agency classified ziram to be "likely to be carcinogenic in humans" based on certain long term studies submitted on ziram. However, further evidence presented by the registrant indicated that the carcinogenicity was due to a contaminant in the industrial formulation of ziram used in the cancer studies. A subsequent study showed that ziram has no carcinogenic potential and the Agency has re-classified it as

"suggestive of carcinogenicity." Due to the revised classification of ziram, a quantitative cancer risk assessment is not warranted.

There are some risks to mixer/loader/handlers, but these risks can be mitigated with PPE and packaging. The current REI of 48 hours is appropriate.

There are also risks to non-target organisms, especially to mammals and aquatic organisms.

Dietary Risk from Food

Ziram's dietary risk assessment considered both acute and chronic (non-cancer) risks from residues in food based on field trials. The acute and chronic dietary (food) risks are less than 100% of the aPAD and cPAD for all population subgroups.

The acute risk was estimated first with residues derived from field trials and second, by applying a reduction factor of 0.15 based on a peach washing study. When the reduction factor was applied to the residues of all commodities (except nuts and berries) the maximum acute dietary risk estimates were below the Agency's level of concern for all population subgroups. The washing factor was not applied to nuts and berries because these commodities have minimal residues (low application rates) and were not the major food items used in the DEEM analysis. Since ziram residues are found mostly on the surface of the fruit and are not systemic in nature, applying a reduction factor (0.15) to the acute residues was a practical way to refine the residues in fruits. After applying the reduction factor, the maximum acute dietary risk (% aPAD) estimates were: children, 1-6 years old (57%); all infants, < 1 year old (26%) and U.S. population (14%), all below the Agency's level of concern. The chronic (non-cancer) food exposures, even without applying the reduction factor were below the level of concern for all population subgroups.

Dietary Risk from Drinking Water

Drinking water exposure to ziram can occur through contamination of groundwater and surface water. In the absence of drinking water monitoring data on ziram, the Agency used screening models to derive the estimated drinking water concentrations (EDWC) of ziram. To determine the maximum allowable contribution in the diet from drinking water, the Agency first looks at how much of the overall allowable risk is contributed by food and the difference is considered the contribution from drinking water, and is expressed as drinking water level of comparison (DWLOC). An EDWC that is greater than the DWLOC value exceeds the Agency's level of concern. For ziram, the EDWC for acute assessments is 98 ppb; acute DWLOCs ranged from 73 to 553 ppb and were greater than the EDWC for all population subgroups except for children (1-6 years old) with a DWLOC of 73 ppb. Although modeled EDWCs suggest a risk concern, the Agency believes that this level of risk is considered within an acceptable range, because the surface water EDWCs are calculated using a conservative model combined with the maximum label application rate to give an upper bound estimate. Also, based on discussions with grower groups, registrants, and information on usage, we have found that the maximum label rate is rarely used for ziram applications. Additionally, the mitigation established in this

document (lowering the maximum application rates for crops such as applies, pear, nectarines, and cherries, and the cancellation of aerial applications for some of the high volume crops) are expected to further reduce potential exposure from drinking water.

The chronic (non-cancer) DWLOCs for all population subgroups were greater than the surface water EDWC of 1.98 ppb indicating that the chronic drinking water risk is below the Agency's level of concern.

Residential Risk

Ziram's residential uses are limited to its formulation as a rabbit repellent for outdoor foliar applications to ornamentals and to its incorporation as an in-can preservative in exterior grade latex paints, sealants and caulking. These uses can result in short-term dermal and inhalation exposures to home owners applying rabbit repellant and exterior latex paint with a brush or an airless sprayer. The margin of exposure (MOE) estimated for home owners applying rabbit repellent is greater than the target MOE of 300; therefore the rabbit repellent use of ziram is not a concern. However, there are concerns with some paint scenarios. The application of exterior latex paint with a brush results in an MOE of 350 which is not of concern to the Agency, but the exposure level to an individual using the airless sprayer at an MOE of 74 is a concern to the Agency. To mitigate this risk, the concentration of ziram in exterior latex paint will be reduced to a maximum of 1% which results in an MOE of 302 when a homeowner applies 15 gallons of paint with an airless sprayer. Although there is potential exposure from use of sealants and caulking materials, such exposures are minimal. Residential postapplication exposures from rabbit repellent applied to outdoor ornamental foliage and latex paint applied to exterior surfaces of buildings are considered to be below the Agency's level of concern.

Aggregate Risk

An aggregate risk assessment looks at the combined risk from all available sources.

Acute Aggregate Risk. The acute aggregate risk addresses the combined exposures from dietary residues consumed in a day (food and drinking water) and one day's residential exposure. For ziram, the acute aggregate risk for dietary and residential exposures are considered to be identical to that of the short term aggregate risk (food plus drinking water and short term residential exposure). Thus, a separate acute aggregate risk was not estimated, and the short-term aggregate risk was estimated. These risks are not of concern.

Short Term Aggregate Risk. The short-term aggregate assessment takes into account exposure to food and water plus short-term residential exposure. Dietary (food plus water) exposure does not pose a problem with a maximum aPAD of 57% and EDWC below the DWLOC. The aggregate short term exposure to ziram resulting from food, water and residential use exceeds the Agency's level of concern to the general population subgroup, due primarily to ziram's use as a mold inhibitor in exterior latex paints. As mentioned earlier under residential risk, lowering the concentration of ziram in the latex paint will eliminate unacceptable risks from this route of exposure.

Chronic Aggregate Risk. The chronic (non-cancer) aggregate risk assessment addresses long term exposure to ziram residues in food and water only because ziram's use as a rabbit repellant or its incorporation as an antimicrobial additive in latex paint do not result in long term residential exposure. Therefore, the non-cancer chronic aggregate risk analysis is the same as the chronic dietary analysis and is not of concern with a maximum cPAD of.26% and EDWC below the DWLOC.

Occupational Risk

The Agency assessed occupational exposure to ziram using data from the Pesticide Handlers Exposure Database (PHED). Occupational exposure to ziram is of concern to the Agency, mainly to mixers/loaders who handle liquid and wettable powder formulations for aerial, ground boom and air blast applications. Also, commercial painters who use exterior latex paint containing ziram are exposed to a higher level of risk than the Agency's level of concern. The Agency has concluded that these risks can be mitigated with the following label restrictions in the case of agricultural formulations: (i) packaging wettable powder formulations in water-soluble bags and requiring additional PPEs , (ii) adding a dust/mist respirator to the personal protective equipment (PPE) for mixer and loaders of liquid formulations, and (iii) reducing the maximum single application rates in some high volume crops. For reducing the risk to commercial painters who use airless sprayers to apply exterior latex paints, the concentration of ziram in latex paints will be lowered to a maximum of 1%. The Agency's exposure assessment for the commercial painter was based on a professional painter using 50 gallons of paint per day, and a homeowner using 15 gallons of paint per day. Based on these exposure scenarios, both professional and homeowner painters exceeded the Agency's level of concern.

Postapplication exposures to the agricultural and antimicrobial uses of ziram are not of concern. Although the short- and intermediate-term postapplication risks to farm workers are low, the current re-entry interval (REI) of 48 hours is being retained due to the Toxicity Category I classification for eye irritation.

Ecological Risk

The Agency conducted a screening level ecological risk assessment to determine the potential impact of ziram on non-target terrestrial and aquatic organisms. The assessments used modeling to evaluate exposure. Based on this assessment, ecological risks also are of concern to the Agency. Based on exposure estimates and the toxicity studies submitted by the registrant, ziram has the potential to result in adverse effects to birds, mammals and aquatic organisms. To address these ecological risks, the product labels will be revised to decrease some of the single and seasonal application rates. Additional confirmatory ecological effects studies are required to better characterize chronic exposure to non-target species.

Summary of Mitigation Measures

No mitigation is required to address dietary or drinking water risks. To address residential risk to home owners who use airless sprayers to apply exterior latex paint, the concentration of ziram in the paint must be lowered to a maximum of 1% concentration. Mitigation measures to address occupational risks to agricultural workers are: packaging wettable powder formulations in water-soluble bags, adding a dust/mist respirator to the personal

protective equipment (PPE) for mixer and loaders of liquid formulations, and reducing the maximum single application rates in some high volume crops. To address ecological risks, some single application maximum rates and some maximum seasonal maximum application rates will be lowered.

Conclusions

The Agency is issuing this Reregistration Eligibility Document (RED) for ziram, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any required label changes for products containing ziram. With the addition of the label restrictions and amendments detailed in this document, the Agency has determined that all currently registered uses of ziram are eligible for reregistration.

The risk assessments for ziram are based on the best scientific data currently available to the Agency and are adequate for regulatory decision making. There is a 60-day public comment period for this reregistration determination.

I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment during reregistration. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the Federal Food, Drug and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Although ziram 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. Further, EPA 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. Therefore, for the purposes of this risk assessment, the Agency has assumed that ziram does not share a common mechanism of toxicity with any other chemicals.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC has identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-fold safety factor
- Whether and how to use probabilistic analyses in dietary exposure assessments
- How to interpret “no detectable residues” in dietary exposure assessments
- Refining dietary (food) exposure estimates
- Refining dietary (drinking water) exposure estimates
- Assessing residential exposure
- Aggregating exposure from all non-occupational sources
- How to conduct a cumulative risk assessment for organophosphate or other pesticides with a common mechanism of toxicity

- Selection of appropriate toxicity end-points for risk assessments of organophosphates
- Whether and how to use data derived from human studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes required label changes based on the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list Data Call-In (DCI) information as well as a data matrix, bibliography and background information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides, and in the Public Docket.

II. Chemical Overview

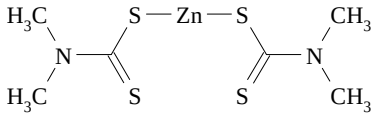
A. Regulatory History

Ziram was first registered in the United States in 1960 as a broad-spectrum fungicide for the control of scab in apples and pears, leaf curl in peaches, and anthracnose and early blight in tomatoes. Additional uses were added to the label in 1981 for controlling leaf blight and scab in almonds, shot-hole in apricots, brown rot and leaf spot in cherries, scab and anthracnose in pecans and leaf spot, rust and powdery mildew in ornamentals. Other registered uses of ziram include homeowner application on residential ornamentals as a rabbit repellent and industrial application as a preservative in exterior latex paints and building materials such as caulking, sealants and wall boards.

Although there are existing tolerances for residues of ziram in beans, Brassica leafy vegetables, leafy vegetables other than Brassica, root and tuber vegetables and strawberries, the registrants have indicated that these uses would not be supported, and have submitted a request to voluntarily cancel these uses. Therefore, these uses were excluded from the dietary risk assessment.

B. Chemical Identification

carbamic acid, dimethyldithio-, zinc salt



Ziram

- Case Number: 2180
- OPP Chemical Code: 034805
- CAS Registry Number: 137-30-4
- Empirical Formula: $C_6H_{12}N_2S_4Zn$
- Molecular Weight: 305.8
- Trade and Other Names: Vancide, Thionic Ziram, etc.
- Basic Manufacturer: Cerexagri, Inc.
- Chemical Family: Dithiocarbamate

Ziram is a white powder with a melting point of 65 ppm in water at 25° C, density of 1.7097 g/mL, an octanol/water partition coefficient (log $P_{ow)}$ of 1.65 at 20° C, and vapor pressure 1.8 x 10^{-5} Pa at 25° C (1.4 x 10^{-7} mm Hg). It is slightly soluble in diethyl ether and ethanol, moderately soluble in acetone, and soluble in dilute alkali, carbon disulfide, and chloroform.

C. Use Profile

The following information is based on currently registered uses of ziram. It has a limited use as an industrial preservative to control microorganisms in latex paints and building materials. Also a small quantity of ziram is used as a rabbit repellent on ornamentals by homeowners.

Type of Pesticide: Ziram is an agricultural fungicide used to control fungal diseases on fruit and nut crops. General use classification

Use Sites

Terrestrial food	Apple, apricot, blackberry, blueberry, boysenberry, caneberries, cherry, loganberry, nectarine, peach, pear, pecan, pepper, quince, raspberry (black, red), strawberry and youngberry

Terrestrial food + feed	Almond, apple, grapes and tomato
Greenhouse food	Tomato
Terrestrial non-food	Christmas tree plantations, ornamental and/or shade trees, ornamental herbaceous plants, ornamental lawns and turf, ornamental nonflowering plants, ornamental woody shrubs and vines
Terrestrial non-food + Outdoor residential	Ornamental and/or shade trees, ornamental herbaceous plants, ornamental non-flowering plants, ornamental woody shrubs and vines
Indoor non-food	Adhesives, industrial; paper/paper products; textiles/textile fibers/cordage
Outdoor non-food	Paints (exterior latex) and Specialty Paints

Target Pests
Disinfectant pests consisting of deterioration and spoilage bacteria and fungi

Plant pathogenic organisms in the following genera as designated as pests on product labels: *Alternaria, Botrytis, Cladosporium, Cercsopora, Coccomyces, Coleosporium, Colletotrichum, Coryneum, Cronartium, Diplocarpon, Erwinia, Erysiphe, Fabraea, Gloeodes, Gloeosporium, Glomerella, Guignardia, Gymnosporangium, Leptosphaeria, Marssonina, Melamspora, Microthyriella, Monolinia, Mycosphaerella, Nectria, Neofabraea, Ovulinia, Peronospora, Pestalotia, Phomopsis, Phragmidium, Phyllactinia, Phyllossticta, Phytophthora, Plasmopara, Pseudomonas, Pseudoperonospora, Puccinia, Puccuniastrum, Sclerotinia, Septoria, Spaerotheca, Taphrina, Uncinula, Uredo, Uromyces, Venturia.*

Fungal diseases of crop plants include alternaria blight, angular leaf spot, anthracnose, bacterial wilt, berry rot, bitter rot, black rot, black spot, botrytis blight, botrytis gray mold, brown rot, bull's-eye fruit rot, bunch rot, canker, cedar-apple rust, downy mildew, early blight, European canker, flower rot, fly speck, fruit molds/rots, fusiform rust, gray mold, large spot, late blight, leaf blister, leaf curl, leaf mold, leaf spot, mummy berry, necrotic ring spot, needle rust, ovulinia petal blight, perennial canker, petal blight, Phomopsis cane blight, Phomopsis twig blight, plum pockets, powdery mildew, ripe rot, rust, scab, shoot blight, shot hole, sooty blotch, stem blight, storage rot and witches broom.

Vertebrate pest - rabbits (as a repellant)

Formulation Types
Dry flowable (Water dispensable granule), flowable concentrate, wettable powder/for dust and wettable powder/for Spray.

Application Methods
Aircraft; ground sprayer; hand held duster; high and low volume ground sprayer; other sprayers; incorporation as an industrial preservative.

Application Timing

Agricultural use: at emergence; bloom; delayed dormant; dormant; fall; petal fall; pink; popcorn; post-harvest; pre-bloom; pre-bloom through foliar; pre-harvest; seedling stage; spring and summer.

Homeowner use: as needed

Industrial preservative: during manufacture

Application Rates: Ziram application rates vary based on crop and disease. Maximum seasonal application rates range from 4.6 to 54.9 lbs ai per acre per season. For specific rate and crop combinations, see the summary in Table 1.

Table 1. Use Profile Summary

Crop	Maximum Rate ai/Acre/App.	Maximum # App./Season	Minimum App. Interval (Days)	Maximum Rate ai/Acre/Season
Almonds	6.1	4	3*	24.3
Apples/Pears (Eastern US)	6.1	7	7	42.6
Apples/Pears (Western US)	6.1	4	10	24.3
Apricots	6.1	5	7	30.4
Blackberries	2.3	1	--	2.3
Blueberries	2.3	2	7	4.6
Cherries (Eastern US)	6.1	5	7	30.4
Cherries (Western US)	4.6	4	5	22.8
Ornamentals	6.1	NA	7	--
Grapes	3.0	7	7	21.0
Peaches/ Nectarines (Eastern US)	6.1	9	7	54.9
Peaches/ Nectarines (Western US) Dormant Appl.	6.1 7.6	7 --	3* --	42.6 –
Pecans	6.1	8	14	48.6
Tomatoes	3.0	6	7	18.2

Note: * Only under certain circumstances such as very warm humid conditions

D. Estimated Usage of Ziram

This section summarizes the best estimates available for many of the agricultural uses of ziram based on available usage information for 1987 - 1997. A full listing of all uses of ziram, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data,

reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 1.9 million lbs a.i. of ziram are used annually, according to the Agency and registrant estimates.

Table 2. Estimated Usage on Major Crops

Crop	Active Ingredient (000 lbs) Applied (Wt. Avg.)[1]	Treated Area (000 Acres) (Wt. Avg)	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Almonds	763	212	62	49
Apple	560	106	22	18
Pecans	160	40	20	8
Peaches	150	30	27	13
Pears	130	23	37	29
Grapes	66	20	4	2
All Others	121	23	--	--
Total	1,950	454	--	--

1. Weighted Average is based on data for 1987-1997; the most recent years and more reliable data are weighted more heavily.

III. Summary of Human Health and Ecological Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for ziram, as presented fully in the documents, *"Ziram Health Effects Division (HED) Risk Assessment for the Reregistration Eligibility Decision (RED) Document" dated 02/10/2003 and "Environmental Fate and Effects Division (EFED) RED Chapter for Ziram" dated 10/10/2001*. EPA issued its preliminary risk assessments for ziram and its salts on July 2001 (Phase 3). This comment period closed in May 2002. In response to the comments and studies submitted during Phase 3, the human health risk assessment was updated and refined. Since there were no significant comments received regarding the ecological risk assessment, the EFED risk assessment was not revised.

The purpose of this document is to summarize the key features and findings, in order to help the reader better understand the conclusions reached in the ziram risk assessment. While the entire risk assessments and related addenda are not included in this document, they are available on the Agency's web site at *www.epa.gov/pesticides,* and in the Public Docket maintained by OPP.

A. Human Health Risk Assessment

1. Dietary Exposure From Food

a. Hazard Profile

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database for ziram is largely complete with respect to the OPPTS Guideline requirements and is adequate to support a reregistration eligibility determination for all currently registered uses. Some data gaps exist; but, these data are considered confirmatory. Further details on the toxicity of ziram can be found in the *HED Toxicology Chapter for the Reregistration Eligibility Decision Document (RED) dated 09/25/2001*.

Acute toxicity values and categories for the technical grade ziram are summarized in Table 3.

Table 3. Acute Toxicity of Technical Ziram

OPPTS Guideline No.	Study Type	Results	Toxicity Category
870.1100	Acute oral MRID Nos. 413404-01	LD_{50} =320 mg/kg (M & F)	II
870.1200	Acute dermal MRID Nos. 413404-02	LD_{50} > 2000 mg/kg (M & F)	III
870.1300	Acute inhalation MRID Nos. 414420-03	LC_{50} = 0.07 mg/l (M & F)	II
870.2400	Primary eye irritation MRID Nos. 416430-01	Severe irritant	I
870.2500	Primary skin irritation MRID Nos. 416430-02	Not an irritant	IV
870.2600	Dermal sensitization MRID Nos. 416420-03	Moderate dermal sensitizer	--

The mechanism of ziram-induced toxicity has not been fully investigated. The primary target organs appear to be the nervous system, liver and thyroid. When administered orally, ziram is rapidly absorbed, distributed, and excreted within 72 hours with a negligible amount being distributed throughout the body. The tissue distribution and excretion data suggests minimal dermal absorption. A single oral dose causes neurological impairments while repeated short term exposure results in inhibition of brain cholinesterase and brain neurotoxic esterase in rats. Liver histopathology, sometimes accompanied by increases in hepatic serum enzyme levels, was seen at various doses in the subchronic and chronic rat studies and in the mouse carcinogenicity study.

Ziram is currently classified as “suggestive of carcinogenicity” to humans. In a previous assessment ziram had been classified as "likely to be carcinogenic in humans." based on older studies done with material that contained contaminants. On December 5, 2002, the Agency re-evaluated the carcinogenic potential of ziram to incorporate newly received information. In follow up studies submitted to the Agency, the long-term dietary administration of a purified sample of ziram resulted in an increased incidence of thyroid C-cell tumors in male rats and pulmonary alveolar/bronchiolar tumors in female mice. No effect was observed in female rats or male mice. This was supported by the evidence showing positive results, but only when the purity of ziram was <90%. Based on the occurrence of C-cell thyroid tumors and hemangiomas in male rats and lung tumors in female mice, ziram was classified into a category “suggestive of carcinogenicity” according to the Agency’s Draft Guidelines for Cancer Risk Assessment (July, 1999). Due to the revised classification of ziram from likely to be carcinogenic in humans to the category of suggestive of carcinogenicity, a quantitative cancer assessment is not required (Report of the Cancer Assessment Review Committee, Jessica Kidwell, 02/06/03).

Based on the acceptable *in vitro* data obtained with purified ziram, an *in vivo* concern is not apparent. This is supported by the evidence showing positive results but only when the purity of ziram is <90%. Test material purity should also be considered for the *in vivo* genetic toxicology data. Ziram consistently induces gene mutations in *Salmonella typhimurium*, however, this finding is not predictive of carcinogenesis because noncarcinogenic dimethyldithiocarbamates are also positive for gene mutations in *S. typhimurium*. There is no concern for mutagenicity at this time.

Food Quality Protection Act Safety Factor: The FQPA safety factor (as required by the Food Quality Protection Act of August 3, 1996) is intended to provide up to an additional 10-fold safety factor (10x), to protect for special sensitivity in infants and children to specific pesticide residues in food or to compensate for an incomplete database. The FQPA Safety Factor is necessary for the ziram due to an incomplete toxicity database because morphometric analysis is lacking from the neurotoxicity test. However, the FQPA safety factor can be reduced to 3x because: (i) there is no quantitative or qualitative evidence of increased susceptibility following an *in utero* exposure to rats and rabbits and/or following pre- and postnatal exposures to rats in the standard developmental and reproduction studies with ziram; (ii) with respect to the data gaps identified in the toxicity data base for ziram, the outstanding data from the Developmental Neurotoxicity Test (morphometric analysis) may confirm and characterize the effects seen with ziram - but not increase the concern for the effects and (iii) the dietary (food and drinking water) and residential exposure assessments will not underestimate the potential exposure to infants and children. The Agency also concluded that the 3x FQPA safety factor will be applicable to all population subgroups when assessing dietary and residential exposures of all durations since there is quantitative evidence of increased susceptibility in the developmental neurotoxicity study in rats.

b. Toxicity Endpoints and Doses Selected For Dietary Exposure

For this risk assessment, the Agency has selected the toxicity doses based solely on endpoints from animal studies. The endpoints (clinical signs) for assessing the acute dietary risk

to the general population and other subgroups were based on the lowest observed adverse effect level (LOAEL) from an acute oral neurotoxicity study in rats. An uncertainty factor (UF) of 100 (10x to account for intra- and another 10x to account for interspecies variations in toxicity) and the 3x FQPA safety factor was applied to all dietary assessments. For the acute dietary exposure assessment scenario, an additional 3x was applied because a NOAEL was not established.

The toxicity endpoint for the chronic dietary risk assessment was based on a no observable adverse effect level (NOAEL) from an oral toxicity study in dogs. The uncertainty factor (UF) of 100 (10x to account for intra- and another 10x to account for interspecies variations in toxicity) and the 3x FQPA safety factor were applied to the chronic assessment.

Dietary exposure estimates are expressed in mg/kg body weight/day and as a percent of the acute/chronic Population Adjusted Dose (a/cPAD) which is the RfD taking into account the FQPA safety factor and appropriate uncertainty factors. This procedure is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed EPA's risk concern.

There is a high degree of confidence in the quality of data and in the hazard and dose response assessments for ziram. Table 4 summarizes the toxicity doses, endpoints and PAD selected for use in this human health risk assessment.

Table 4. Toxicological Endpoints and Other Factors Selected in the Dietary Risk Assessment of Ziram.

Exposure Scenario	Dose	Endpoint	Study	PAD
Acute dietary	LOAEL = 15 mg/kg/day FQPA SF = 3 UF = 300 RfD = 0.05 mg/kg	Ataxia and slight impairment of gait	Acute oral neurotoxicity - rat MRID No. 433628-01	0.017 (mg/kg/day)
Chronic dietary	NOAEL = 1.6 mg/kg/day FQPA SF = 3 UF = 100 RfD = 0.016 mg/kg	Decreased body weight gain	52 - week oral toxicity - dog MRID No. 428239-01	0.005 (mg/kg/day)

c. Dietary Exposure Assumptions

Dietary exposure to Ziram residues may occur as a result of use of ziram on fruits, and nut and vegetable crops. With the exception of nuts all commodities for which ziram is registered are considered high consumption food items for infants and children.

The Agency conducted highly refined probabilistic acute and chronic dietary risk assessments for all current uses of ziram. These exposure assessments were conducted using the dietary exposure and evaluation model (DEEM™) system, developed by Novigen Sciences, Inc. DEEM^{tm} calculates acute and chronic dietary exposure estimates to residues in food for the U.S. general population and various population subgroups. The software contains food consumption data from the USDA continuing survey of food intake by individuals (CSF II) from 1989-1992.

For the acute dietary risk assessment, the entire distribution of a single day's food consumption data for each subpopulation is combined with distribution of residues in a probabilistic analysis (referred to as a "Monte Carlo" Analysis) to obtain a distribution of exposure in mg/kg/day. For ziram, this assessment reflects the use of residues from field trial data on all crops where such data are available and tolerance level data when field trial data was not available. Ziram residues are found on the surface of the fruit and are not systemic in plants. Therefore, use of a factor due to washing is a viable way to refine the risk estimates in calculating dietary risk; a washing factor of 0.15x from the peach washing study was applied to the residues while estimating acute exposures from food.

For chronic exposure, the 3-day average of the consumption data for each subpopulation is combined with average residues on commodities to determine the average exposure in mg/kg/day. Chronic dietary risks were calculated using the dose (NOAEL), DEEM™, average residues from field trial data, percent crop treated, UF and FQPA Safety Factor. In this risk assessment, dietary exposure assessments were performed based on residues of ziram on fruit, nut and vegetable crops derived from field trials.

Based on the Agency's cancer classification of ziram as "suggestive of carcinogenicity to humans," a quantitative assessment of human carcinogenic risk is not required. Additionally, the chronic PAD is protective of all toxic effects including cancer.

d. Acute Exposure From Food

The acute exposure to ziram from food is reported as a percentage of the aPAD for the 99.9th percentile of the population. The % aPAD estimated for the various population subgroups is provided in Table 5.

Table 5. Estimated Acute and Chronic Food and Risk for Ziram

Population Subgroup	Acute Risk		Chronic Risk	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% cPAD
U.S. population	0.0025	15	0.0003	6
All infants < 1 year	0.0045	26	0.0014	28
Children 1-6 yrs	0.0097	57	0.0009	18
Children 7-12 yrs	0.0036	21	0.0006	12
Females 13-50 yrs	0.0017	10	0.0002	4
Males 13-19 yrs	0.0012	7	0.0002	4
Males 20+	0.0016	9	0.0002	4

% PAD = (Exposure ÷ PAD) x 100%. The aPAD and cPAD for the U.S. Population are 0.017 mg/kg/day and 0.005 mg/kg/day, respectively (Table 4).

e. Chronic (Non-Cancer) Exposure From Food

The chronic dietary exposure to ziram was calculated using average residues from crop field trials, percent crop treated and average food consumption and was compared to the cPAD. The resulting risk estimates did not exceed 28% of the cPAD for any subpopulation; therefore, the chronic risks are below the LOC of 100% for all population subgroups (Table 5).

f. Cancer Risk From Food

A quantitative assessment of human carcinogenic potential for ziram is not required because it is classified as "suggestive of carcinogenicity" to humans.

2. Dietary Exposure From Drinking Water

Pesticide exposure from drinking water can occur through surface and ground water contamination. For this assessment, the Agency considered acute (one day) and chronic (lifetime) drinking water risks by using models in the absence of actual monitoring numbers to estimate those risks. The models used were (i) pesticide root zone model exposure analysis model system (PRZM/EXAMS) to estimate surface water concentrations and (ii) screening concentrations in ground water (SCI-GROW) to estimate groundwater concentrations of ziram. Both these models are considered to be screening tools, with the PRZM/EXAMS (Tier II) being more refined than SCI-GROW (Tier I). These models take into account the environmental profile of a pesticide and its use patterns. The primary use of these models by the Agency at this stage is to provide a screen for assessing whether a pesticide is likely to be present in raw drinking water at concentrations that would exceed human health levels of concern.

Ziram is not regulated under the Safe Drinking Water Act; therefore, neither a maximum contaminant level (MCL) nor a drinking water health advisory has been established by the EPA's Office of Water. No other sources of information on monitored concentrations of ziram in surface water or ground water are known to exist. In the absence of monitoring data, Estimated Drinking Water Concentrations (EDWCs) of ziram in surface and ground water were generated using the PRZM/EXAM and SCI-GROW models.

Surface water: After aerial and ground applications to crops, ziram residues can be transported to surface water via run-off and spray drift. To estimate the surface water concentrations, the PRZM/EXAMS modeling was conducted applying the environmental fate parameters such as aerobic and photodegradation half-lives and binding coefficients and used the maximum dormant application rate of 7.5 lb ai/A at a frequency of 2 applications at 60 days interval and a crop cycle application rate of 6.1 lb ai/A at a frequency of 7 applications at 3 days interval on peaches in the Western U.S. The acute EDWC (peak) and the non-cancer chronic (annual average) surface water concentrations of ziram are estimated to be 98 parts per billion (ppb) and 1.98 ppb, respectively (Table 6).

Table 6. Estimated Drinking Water Concentrations of Ziram in Surface and Ground Waters

Model	EDWC
Surface water (PRZM/EXAMS)	Acute = 98 ppb (peak) Chronic = 1.98 ppb
Groundwater (SCI-GROW)	Chronic = 0.03 ppb

Ground Water: The likely concentrations of ziram in ground water, estimated using the SCI-GROW model, considered the pesticide use at the maximum allowable rate in areas where groundwater is vulnerable to contamination. In most cases, a large majority of the use area will have groundwater that is less vulnerable to contamination than the areas used to derive the SCI-GROW model. The input values for the SCI-GROW included the environmental fate parameters and the maximum seasonal application rate on peaches and nectarines (Western U.S.) at 6.08 lb ai/acre at a frequency of 7 applications at 3 day interval. The EDWC for ziram in ground water estimated to be 0.03 ppb (Table 6).

a. Drinking Water Exposure Characterization

To determine the maximum allowable contribution of pesticide residues in water, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed the level of concern.

The current estimate of residues in drinking water by PRZM/EXAMS and SCI-GROW are compared to DWLOC values for each of the population subgroups. If the model estimates from PRZM/EXAMS and SCI-GROW do not exceed the DWLOC, it can be concluded with reasonable certainty that the contribution from pesticide residues in drinking water does not exceed the Agency 's LOC. On the other hand, if the estimated acute, short term or chronic dietary risk for a pesticide from the food alone exceed the Agency 's level of concern, then there is no allowable contribution for drinking water in the risk cup; then the drinking water contribution is considered exceeding the LOC. Table 7 summarizes the drinking water contributions for acute exposures for all the population subgroups.

Table 7. Acute Exposure From Drinking Water from Surface and Ground Water

Population Subgroup	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	$DWLOC_{Acute}$ (μg/L)*	Acute Surface Water EDWC (μg/L)	Acute Ground Water EDWC (μg/L)
US Population	0.0025	0.0145	508	98	0.03
All Infants	0.0045	0.0125	125	98	0.03

Population Subgroup	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	$DWLOC_{Acute}$ (μg/L)*	Acute Surface Water EDWC (μg/L)	Acute Ground Water EDWC (μg/L)
Children 1-6	0.0097	0.0073	73	98	0.03
Children 7-12	0.0036	0.0134	201	98	0.03
Females 13-50	0.0017	0.0153	459	98	0.03
Males 13-19	0.0012	0.0158	553	98	0.03
Males 20+	0.0016	0.0154	539	98	0.03

* $DWLOC_{Acute}$ = [acute water exposure (mg/kg/day) x (body weight)] / [consumption (L) x 10^{-3} mg/μg].

For all population sub-groups except for children 1 to 6 years, the DWLOC values are higher than the surface water EDWC, indicating that acute exposure to ziram in drinking water is not a concern. In the case of children, the one-day maximum exposure to ziram in surface water slightly exceeds the Agency's LOC. However, this level of risk is considered acceptable for ziram because the surface water model used is a conservative screening tool and high end exposure scenarios were used for the EDWC estimation of ziram. Also the revised application rates and cancellation of aerial applications in some high volume crops are expected to further reduce the exposure from drinking water. The short term DWLOC was considered to be the same as the acute DWLOC described above.

For all population sub-groups, the DWLOC values are higher than the modeled ground water EDWC, indicating that acute exposure to ziram in drinking water from ground water sources is not a concern

Chronic Drinking Water Risk: $DWLOC_{Chronic}$ was estimated similar to the $DWLOC_{Acute}$, except chronic PAD and chronic food residue contribution were used (Table 8).

Table 8 . Chronic Exposure From Drinking Water

Population Sub-group	Chronic Food Exposure (mg/kg/day) [1]	Chronic Water Exposure (mg/kg/day) [2]	$DWLOC_{Chroic}$ (μg/L) [3]	Chronic Surface Water EDWC (μg/L)	Chronic Ground Water EDWC (μg/L)
US Population	0.0003	0.0047	165	1.98	0.03
All Infants	0.0014	0.0036	36	1.98	0.03
Children 1-6	0.0009	0.0041	41	1.98	0.03
Children 7-12	0.0006	0.0044	44	1.98	0.03
Females 13-50	0.0002	0.0048	144	1.98	0.03
Males 13-19	0.0002	0.0048	168	1.98	0.03
Males 20+	0.0002	0.0048	165	1.98	0.03

1. Chronic food exposure values from Table 5.
2. Water exposure = cPAD - Food exposure

3. $DWLOC_{Chroic}$ = [chronic water exposure (mg/kg/day) x (body weight)] / [consumption (L) x 10^{-3} mg/μg].

As shown in Table 8, the chronic DWLOCs for all population subgroups are higher than the surface and ground water chronic EDWCs; therefore, chronic drinking water exposure is not a concern.

3. Residential Risk

The residential use of ziram is limited to outdoor foliar application to ornamentals as a rabbit repellant and as an in-can preservative in exterior latex paint. Use of ziram as a rabbit repellent (Bonide Rabbit Scat; EPA Reg. No. 4-403) applied as a foliar dust or spray application to residential outdoor ornamentals can result in dermal and inhalation exposures to homeowners. This type of exposure is being treated as short-term exposure lasting a few days, as no long-term or chronic exposure is expected from this type of use.

Residential applications of the exterior grade latex paint containing ziram (Vancide MZ-96; EPA Reg. No. 1965-79) include painting with an airless sprayer and paint brushes (paint roller exposure data are not available but the magnitude of exposure is believed to be similar to that monitored for use of a paint brush). The homeowner exposure was estimated using a single scenario based on the painters wearing short-sleeved shirts and short pants (i.e., common homeowner attire during the pesticide application). In addition, only short-term exposures are assessed, because the Agency does not believe homeowners who apply paints containing ziram will be exposed to the product for more than seven days.

The Agency has estimated the residential handler exposure using data from the Pesticide Handlers Exposure Database (PHED, version 1.1), a surrogate carbaryl duster study, as well as the toxicological endpoints of ziram. For homeowner/handler exposure assessments, the Agency does not believe a tiered mitigation approach like those used for assessing occupational handler risk to pesticides is appropriate. Homeowners often lack access to personal protective equipment (PPE) and also do not possess expertise in the proper use of PPE. Risk for this potentially exposed population is measured by a MOE which determines how close the residential exposure comes to a NOAEL. Generally, a target MOE of 100 is used to estimate the LOC under residential scenarios; however in this instance, the short-term residential risk assessments for homeowners using rabbit repellent and paint containing ziram, applied an UF 100 and an additional FQPA Safety Factor of 3x for a target MOE of 300. The Agency has concluded that an additional 3x FQPA safety factor is applicable to all population subgroups when assessing residential exposures of all durations since there is quantitative evidence of increased susceptibility in the developmental neurotoxicity study in rats.

a. Toxicity for Residential Risk Assessment

The doses and endpoints selected for the residential risk assessment are provided in Table 9. Dermal and inhalation risks can be combined since they are based on the same endpoint.

Table 9. Toxicological Doses and Endpoints in the Residential Risk Assessment

Exposure Scenario	Dose [1, 2]	Endpoint	Study	Absorption Rate
Dermal: Short - and Intermediate term	NOAEL = 7.5 mg/kg/day FQPA SF = 3 UF = 100 MOE = 300	Increased incidence of resorption and post implantation loss	Prenatal oral development - rabbit MRID 001613-16	1 %[3]
Inhalation: Short- and intermediate term	NOAEL = 7.5 mg/kg/day FQPA SF = 3 UF = 100 MOE = 300	Increased incidence of resorption and post implantation loss	Prenatal oral development - rabbit MRID 001613-16	100 %

1. MOE = Margin of exposure (UF x FQPA SF).
2. The Target MOE (Residential) = 300. The Agency has concluded that the 3x FQPA safety factor is applicable to all population subgroups when assessing residential exposures of all durations because there is quantitative evidence of increased susceptibility in the developmental neurotoxicity study in rats.
3. The dermal adsorption rate of 1% was derived from the ratio of LOAELs in the rabbit oral developmental study and the 21-day dermal rabbit study.

b. Residential Exposure Scenarios and Assumptions

Table 10 summarizes the short-term exposures of ziram to homeowners. The rabbit repellent use of ziram as a dust and liquid can result in short term dermal and inhalation exposures to mixers/loaders/applicators. This use scenario is expected to result in minimal exposures as indicated by MOEs of 1442 (for dust) and 5910 (for spray), against a target MOE of 300.

Table 10. Short-term Exposure to Residential Users from the Use of Ziram as a Rabbit Repellent and in Exterior Latex Paint.

Application method/ Exposure scenario	Application Rate	Unit Exposure [1]	Absorbed Dose [2] mg/kg/day	MOE [3]	Total MOE [4, 5]
EXPOSURES FROM RABBIT REPELLENT USE					
Dust: Loading/applying Dermal Inhalation	1 can (10 oz) 0.14 lb ai -- –	 140 mg/lb ai 1.2 mg/lb ai	 0.0028 0.0024 Total = 0.0052	 2679 3125	 1442
Spray: Low pressure hand wand Dermal Inhalation	2.5 gal liquid 0.035 lb ai/gal -- –	 100 mg/lb ai 0.03 mg/lb ai	 0.0012 0.000037 Total = 0.0012	 6087 >200,000	 5910
EXPOSURES FROM IN-CAN PRESERVATIVE USE					
Painting: Using a brush Dermal Inhalation	2 gal/day -- --	 230 mg/lb ai 0.28 mg/lb ai	 0.019 0.0023 Total = 0.0213	 394 3233	 351
Painting: Airless sprayer Dermal Inhalation	15 gal/day -- --	 79.0 mg/lb ai 0.83 mg/lb ai	 0.049 0.052 Total = 0.1010	 153 145	 **74**

1. Unit exposures are from a surrogate study in Pesticide Handlers Exposure Database (PHED).
2. Dermal absorbed dose/day = [(unit exposure * Absorption rate from Table 9) * (Application rate * Amount treated / Body weight of 70 kg)]. Inhalation absorbed dose = [(unit exposure * Absorption rate from Table 9) * (Application rate * Amount treated / Body weight of70 kg)].
3. Dermal MOE = (NOAEL/Daily absorbed dose). Inhalation MOE = NOAEL (NOAEL/Daily absorbed dose).
4. Total MOE = (NOAEL/ [Dermal absorbed dose + Inhalation absorbed dose].
5. The target MOE for residential use = 300 (Table 9).

Residential applications of the exterior grade latex paint include painting with an airless sprayer and use of a brush. Although there is potential exposure during the handling of caulks and sealants containing ziram, the Agency has not estimated exposure and concomitant risk because such exposures are considered neglible. It is the Agency 's judgement that among the uses of ziram as an antimicrobial agent, painting scenarios represent the high-end exposure as compared with exposure to caulks and sealants. For homeowners, the short-term dermal and inhalation exposures to individuals exposed while using an airless sprayer are of concern; however, similar exposure from using a paint brush is not because the amount of material that can be applied is greater with the sprayer. The combined dermal and inhalation MOEs are 74 for the airless sprayer and 351 for the paint brush (Table 10), while the target MOE is 300. No mitigation measures, such as the use of chemical resistant gloves or respirators are available for the homeowners because there are no provisions to label paint cans to prevent ziram exposure.

c. Residential Postapplication Exposure

The postapplication exposures of ziram to both adults and children are expected to be minimal when used as a rabbit repellent on outdoor ornamentals and as an *in-can* preservative in the exterior grade latex paint. Ziram's low vapor pressure (1.4E-7 mm Hg at 25° C) and the low potential dermal contact with treated surfaces such as exterior painted surfaces, adhesives, and caulks are factors that are responsible for minimal postapplication exposures.

4. Aggregate Risk

Aggregate exposure is the total exposure to a single chemical that may occur from dietary (food and drinking water), residential and other non-occupational sources and from all known or plausible exposure routes (oral, dermal and inhalation). The FQPA amendments to the FFDCA, §408(b)(2)(A)(ii) require that for establishing or leaving in effect a pesticide tolerance "there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residues from all dietary sources and other exposures for which there are reliable information. Aggregate risk assessments are conducted for acute (1 day), short-term (1-30 days), intermediate-term (30 days to several months) and chronic (several months to lifetime) exposures.

The Agency considered aggregate exposure and risk estimates for residents who might be exposed to ziram from multiple sources, such as food, drinking water and residential use. Residential exposure and risk from the use of ziram was limited to short-term exposure scenarios (dermal and inhalation) because intermediate-term and chronic residential exposure to ziram from the rabbit repellent and it's use in paint are not expected to occur.

a. Acute Aggregate Risk

The acute aggregate risk assessment addresses the combined exposure to ziram residues in food and water consumed in a single day. As discussed previously, comparison of the acute DWLOCs with the environmental concentrations shows that estimated surface and groundwater concentrations of ziram are less than the DWLOCs for all populations, except children 1 to 6 years old. As discussed earlier, the risk to children 1 to 6 years old is considered to be acceptable for ziram because the surface water model used is a conservative screening tool and high end exposure scenarios were used for the EDWC estimation of ziram.

b. Short Term Aggregate Risk

The short-term aggregate risk estimate includes chronic food, drinking water and short-term residential exposures from the uses of ziram. Under the residential conditions, no oral exposure to ziram is expected to occur. Short term dermal and inhalation exposures are possible to the homeowners who apply rabbit repellent on outdoor ornamentals or apply exterior grade latex paint with a brush or airless prayer. Since the short term residential risk for homeowners painting with an airless sprayer results in an MOE of 74, indicating a risk of concern, a short

term aggregate MOE combining food, water and residential exposures was not calculated for homeowners painting with an airless sprayer.

Chronic residential exposure scenarios is not expected to occur.

Table 11 and Table 12 summarize the short term aggregate risk from food and residential exposures and short-term DWLOC estimates to the general population, respectively. The short-term aggregate risk is not a concern (MOEs are > Target of 300) when homeowners apply rabbit repellent dust to ornamentals or apply exterior latex paint using a brush (Table 11). Similarly, according to the water estimates, the ziram drinking water residue contribution to the chronic aggregate risk also is not significant as DWLOCs for both types of uses are more than the ground and surface water EDWCs (Table 12).

Table 11. Short-Term Aggregate Risk to Residential Ziram Uses.

Homeowners Using	Food Exposure mg/kg/day [1]	Residential Exposure mg/kg/day [2]	Aggregate Exposure mg/kg/day [3]	Aggregate MOE [4]
Rabbit Repellent Dust	0.0003	0.0052	0.0055	1358
Paint with Brush	0.0003	0.0213	0.0216	347

1. Food exposure from Table 8
2. Total absorbed dose from Table 10.
3. Aggregate exposure (food + residential).
4. Aggregate MOE = NOAEL (7.5 mg/kg/day) ÷ Aggregate exposure.

Table 12. Short-Term DWLOC for Residential Ziram Uses.

Home owners Using	Max. Exposure mg/kg/day [1]	Max. Water Exposure mg/kg/day [2]	Ground Water EDWC μg/L [3]	Surface Water EDWC μg/L [3]	Short -term DWLOC μg/L [4]
Rabbit Repellent Dust	0.025	0.0195	0.03	98	680
Paint with Brush	0.025	0.0034	0.03	98	120

1. Maximum exposure = NOAEL / Target MOE
2. Maximum exposure (Column 1) - (Food + Residential exposures from Table 11)
3. EDWC at the maximum application rate of ziram.
4. DWLOC = [Water exposure (mg/kg/day) x (body weight)] / [consumption (L) x 10^{-3} mg/μg].

Negligible short term aggregate post application exposures for both children and adults are expected from the rabbit repellent or exterior latex paint uses, due to the low vapor pressure of ziram and due to the low dermal contact potential to treated surfaces. Therefore, a short term aggregate post application risk assessment is not necessary.

c. Intermediate Term and Chronic (Non-cancer) Aggregate Risk

For this risk assessment, only chronic dietary exposure is expected. No intermediate term and chronic residential exposure scenarios were identified after painting the exterior of a

house with the latex paint and treating the outdoor ornamental plants with Rabbit Scat. Therefore, separate intermediate term and chronic aggregate risks were not assessed. Chronic dietary (food and water) risks are not of concern.

d. Cancer Aggregate Risk

Ziram is currently classified as "suggestive of carcinogenicity" to humans, therefore, a quantitative cancer assessment is not required (Report of the Cancer Assessment Review Committee, Jessica Kidwell, 02/06/03).

5. Cumulative Risk

The FQPA (1996) stipulates that when determining the safety of a pesticide chemical, the Agency shall base its conclusions on risks posed by the chemical on available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

Ziram 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. While additional evaluation of possible cumulative effects of ziram and other substances that may have a common mechanism of toxicity is necessary, for the purposes of this risk assessment, EPA has assumed that ziram does not share a common mechanism of toxicity with other pesticides.

6. Occupational Risk

Occupational exposure to ziram may occur from agricultural/ornamental crops and antimicrobial uses. In agriculture, occupational workers may include individual farmers or growers and professional or custom pesticide applicators. They can be exposed during mixing/loading and applying formulations containing ziram on agricultural, ornamental (other than rabbit repellent use) and commercial/industrial settings or re-entering the treated areas. The use of ziram as a rabbit repellent is a homeowner use and was not included in the occupational

assessment. Use of ziram as an industrial preservative results in two types of occupational exposures: one, to primary handlers at the manufacturing stage when ziram is added to the paints, caulks and sealants and two, to secondary handlers (commercial painters and other workers) who work with ziram containing products such as paints, caulks, and sealants.

To conduct occupational risk estimates for loading powder formulations of ziram at the time of paint and sealant manufacturing, the Agency used surrogate data from the Chemical Manufacturers Association (CMA) antimicrobial exposure study. For the agricultural occupational exposure assessments, the Agency used the Pesticide Handlers Exposure Database (PHED, version 1.1), dislodgeable foliar residue (DFR) data for apples and grapes in conjunction with the Agency's standard values for transfer coefficients based on Agricultural Reentry Task Force (ARTF) data as well as the toxicological endpoints. For details regarding the assumptions and uncertainties identified during the handler exposure assessments, refer to The Agency's's Occupational and Residential Exposure Assessment (ORE) Document (9/12/01).

The toxicological doses, endpoints and other factors used in the occupational risk assessment are listed in Table 13.

Table 13. Toxicological Endpoints and Other Factors Selected for the Occupational Risk Assessment for Ziram

Exposure Scenario	Dose	Endpoint	Study	Absorption Rate*
Dermal: Short- and Intermediate Term	NOAEL = 7.5 (mg/kg/day) UF = 100 Target MOE = 100	Increased incidence of resorptions and post implantation loss	Prenatal oral developmental - Rabbit MRID No. 001613-16	Dermal 1.0%
Dermal: Long Term	NOAEL = 1.6 (mg/kg/day) UF = 100 Target MOE = 100	Decreased body weight gain	52-Week oral toxicity - Dog MRID No. 428239-01	
Inhalation: Short- and Intermediate Term	NOAEL = 7.5 (mg/kg/day) UF = 100 Target MOE = 100	Increased incidence of resorptions and post implantation loss	Prenatal oral developmental - Rabbit MRID No. 001613-16	Inhalation 100.0%
Inhalation: Long Term	NOAEL = 1.6 (mg/kg/day) UF = 100 Target MOE = 100	Decreased body weight gain	52-Week oral toxicity - Dog MRID No. 428239-01	

* The dermal adsorption rate of 1% was derived from the ratio of LOAELs in the rabbit oral developmental study and the 21-day dermal rabbit study.

a. Short- and Intermediate-term Risks to Workers From Agricultural Uses

Agricultural workers (mixers, loaders, applicators and flaggers) are exposed mainly to the dry flowable, liquid- and wettable powder (WP) formulations. The agricultural uses are considered to be of a short- to intermediate-term duration. Handler exposure assessments were performed with increased levels of risk mitigation from PPE to engineering controls (i) baseline attire is long pants, long sleeved shirts, no gloves, no respirators and open cabs; (ii) minimum PPE are long pants, long sleeved shirts, chemical resistant gloves, dust/mist respirators and open cabs, (iii) maximum PPE are coveralls over long pants, long sleeved shirts, chemical resistant gloves, organic vapor respirators and open cabs and (iv) engineering controls include closed mixing/loading systems with enclosed cabs. PPE that goes with engineering controls include long pants, long sleeved shirts, no gloves and no respirators. Agricultural occupational exposure scenarios can be described as short term (1 to 30 days), intermediate term (30 days to six months), and long term or chronic (6 months to life-time). The agricultural/ornamental uses of ziram result in only short- to intermediate-term exposures, which is addressed here. The toxicity endpoints for the short- and intermediate-term dermal and inhalation exposures are based on the same effects, and therefore, the risk estimates were combined.

Both dermal and inhalation exposures are expected to mixers/loaders, applicators and flaggers from applying ziram product formulations. Five of the 25 assessed scenarios showed risks of concern (MOE <100). Table 14 summarizes the short- and intermediate-term exposures to workers when ziram is used in agricultural operations. The data indicate that mixers and loaders wearing baseline PPE (long pants, long sleeved shirts, shoes and socks, no gloves, and no respirator while using open systems) have the highest exposure scenarios when they work with liquid and wettable powder formulations for application by aerial, ground boom and airblast equipment. The MOEs ranged from 8 to 170 while the Target MOE is 100 (Table 14). Upgrading to minimal PPE (Baseline PPE + chemical resistant gloves and dust/mist respirators) provides adequate protection to handle liquid formulations (MOE = 4,600 to 6,000). Even further upgrading to maximum PPE (minimal PPE + coveralls, organic vapor respirators instead of the dust/mist and open cabs) did not provide adequate protection to workers who mix and load WP formulations (MOE = 24 to 35) for aerial application. The occupational exposures to applicators and flaggers are not of concern (Table 14).

Table 14. Short- and Intermediate-term Exposures to Handlers of Agricultural Formulations Wearing Various Levels of PPE.

Formulation [1], Application Equipment and Area Treated [2]	PPE Type	Appl Rate lb ai/A	Dermal		Inhalation		Total MOE [6]
			Dose[3]	MOE [4]	Dose[3]	MOE [5]	
TO MIXER/LOADER							
Dry flowable formulation							
Aerial @ 350 Acres/Day	Baseline	6.08	0.20	370	0.023	320	170
Liquid formulation							
Aerial @ 350 Acres/Day	Baseline	6.08	0.88	9	0.036	210	8
Airblast @ 40 Acres/Day	Baseline	6.08	0.10	74	0.0042	1,800	71
Aerial @ 350 Acres/Day	Minimal	6.08	0.007	1100	0.0073	1000	520
Airblast @ 40 Acres/Day	Minimal	6.08	0.00080	9,400	0.00083	9,000	4,600
Wettable powder formulation							
Aerial @ 350 Acres/Day	Baseline	6.08	1.1	7	1.3	6	3
Airblast @ 40 Acres/Day	Baseline	6.08	0.13	58	0.15	50	27
Aerial @ 350 Acres/Day	Minimal	6.08	0.052	150	0.26	29	24
Airblast @ 40 Acres/Day	Minimal	7.60	0.0074	1000	0.037	200	170
Ground boom, @ 80 Acres/Day	Minimal	3.04	0.0059	1300	0.030	250	210
Aerial @ 350 Acres/Day	Maximum	7.60	0.049	150	0.16	46	35
Airblast @ 40 Acres/Day	Maximum	7.60	0.0056	1300	0.019	400	310
Ground boom, @ 80 Acres/Day	Maximum	3.04	0.0045	1700	0.015	500	390
Aerial @ 350 Acres/Day	Eng.Controls	7.60	0.0037	2000	0.0091	820	580
Airblast @ 40 Acres/Day	Eng Controls	7.60	0.00043	18,000	0.001	7,200	5,100
TO APPLICATOR – any formulation							
Air blast @ 40 A/day	Baseline	7.60	0.016	480	0.020	380	210
High Pressure Hand Wand, @ 1000 gal/Day	Baseline	0.02 lb ai/gal	0.0051	1500	0.023	330	270
TO FLAGGERS							
Aerial @ 350 Acres/Day	Baseline	7.60	0.0042	1800	0.013	560	430

1. Formulation represented are Dry flowable (Ziram 76DF, EPA. Reg. No. 4581-140), Liquid flowable (Ziram 4L, EPA Reg. No. 19713-270) and Wettable Powder (Ziram 76WP, EPA Reg. No. 134704-471).
2. Area treated is based on acres that can be reasonably applied in a single day. Crop scenarios were applications to fruit and nut trees, dormant peaches, tomatoes and ornamentals.
3. Dose refers to the absorbed dose in mg/kg/day
4 & 5. Unit exposures for dermal and inhalation are from PHED Surrogate Exposure Guide dated August, 1998
6. Target MOE = 100.

The quantitative cancer assessment for occupational exposure is no longer applicable because the cancer classification has been revised from likely to be carcinogenic in humans to the category of suggestive of carcinogenicity. For more information see the section III. A. 4.d.

Postapplication Exposure From Agricultural Uses

Several levels of postapplication exposure activities have been identified ranging from low exposure activities such as weeding and scouting in immature plants to high exposure activities such as harvesting or thinning of fruit. The short- and intermediate-term postapplication assessments indicate that the potential restricted entry interval (REI) (i.e., the day after treatment that the MOEs reaches 100), based on the toxicity of the active ingredient, is 0 days for all crops and all activities. Although MOEs of 100 are achieved for all crops and all activities on day 0, because ziram is an acute Toxicity I category for eye irritation (Table 1), the current REI of 48 hours is appropriate.

b. Short- and Intermediate-term Risks to Handlers From Antimicrobial Uses

Vancide MZ-96 (EPA Reg. No. 1965-79) is an industrial preservative containing 96% ziram formulated as a wettable powder. Use of ziram as an industrial preservative results in two types of exposures: one to primary handlers at the manufacturing stage of end use products and two, to secondary handlers (commercial painters) when ziram containing paints are applied on to exterior surfaces.

The product label of Vancide MZ-96 describes two types of uses by the commercial formulators: One use is as a general preservative/mold inhibitor during the initial phase of the manufacturing process in adhesives, caulks, sealants, and wallboard at 0.185 to 0.5%. The second use of Vancide MZ-96 is to add it to the exterior latex paints as an in-can preservative at 1-3%. Although there is potential exposure working with ziram treated materials (e.g., caulks and sealants), they are not included here because such exposures are considered negligible. It is the Agency's professional judgement that the painting scenarios represent the high end exposures for ziram's antimicrobial secondary uses. For a complete discussion of assumptions used in the painter scenarios, refer to the Occupational and Residential Exposure Assessment dated September 12, 2001. The short- and intermediate term occupational exposures to manufacturing workers and commercial painters are estimated in Table 15.

Handler and postapplication antimicrobial exposures are defined by the Antimicrobial Division (AD) as *"primary"* and *"secondary"* handlers. The primary handlers are defined by the Agency as those individuals exposed to the formulated product (e.g., adding the ziram-containing product, Vancide MZ-96 formulation into vats of paint during the manufacturing process). The secondary handlers are defined by the Agency as those individuals exposed to the active ingredient as a direct result of its incorporation into an end use product (e.g., commercial painters applying ziram-treated exterior latex paint that in itself is not a registered product).

Table 15. Short- and Intermediate-term Exposures to Primary and Secondary Handlers When Ziram is Used as an Antimicrobial in Sealants and Paints

Exposure Scenario [1]	Maximum Appl. Rate (lb ai/gal) [2]	Amount Treated [3]	Dermal MOE [6]	Inhalation MOE [7]	Total MOE [8]
Loaders for General Preservative use	0.065	1,000 gal	1,700	3,200	1,100
Loaders for Paint Use	0.29	1,000 gal	390	720	250
Painters using Airless Sprayer	0.29	50 gal	95	44	**30**
Painters Using Paint Brush	0.29	5 gal	200	1,300	170

Notes:

1. Loaders are the primary handlers who are factory workers adding Vancide MZ-96 to paints and sealants during the manufacturing stage. Painters are secondary handlers who use an airless sprayer and brush to apply the paint.
2. Maximum application rates are based on the Vancide MZ- 96 label (EPA Reg. No.1965-79) along with density and % solid information from Vanderbilt Co.
3. Amount treated are estimates from EPA's AD and The Agency's's Residential SOPs.
4. Unit exposures for dermal and inhalation are from CMA study and PHED.
5. Dermal absorbed dose (mg/kg/day) = [unit exposure (mg/lb ai) * 0.01 dermal absorption rate* max. appl. rate (lb ai/gallon) * gallons handled / body wt (70 kg).
6 MOE = NOAEL (7.5 mg/kg/day) / daily absorbed dose by dermal or inhalation routes.
7. Inhalation absorbed dose (mg/kg/day) = [unit exposure (μg/lb ai) * 0.001 mg/μg unit conversion * inhalation absorption rate] * max. Appl. rate (lb ai/gal) * gallons handled / body weight (70 kg).
8. Total MOE = NOAEL (7.5 mg/kg/day/ (absorbed dose by dermal + inhalation). Target MOE is 100.

To calculate the occupational risk estimates for antimicrobial use, the Agency has used surrogate data for loading powder formulations of ziram from the Chemical Manufacturers Association (CMA) antimicrobial exposure study and Pesticide Handlers Exposure Database (PHED).

During the general preservative use, the short- and intermediate-term total MOE for the primary handlers wearing long pants, long sleeved shirts, shoes and socks, chemical resistant gloves, and a dust/mist respirator was estimated to be 1,100 (Table 15).

According to the manufacturer, factory workers of paints and sealants handle ziram approximately every other week at a frequency of 5 days per week (Memorandum dated August 16, 2001 from Vanderbilt Co.). This type of intermittent exposure frequency is not considered a chronic exposure scenario (i.e., greater then 180 days) because ziram is not used continuously for 180 days. Also, available data indicate that urinary and fecal excretion of ziram is nearly complete within 72 hours at low-doses and within 96 hours at high-doses in a rat metabolism study. Therefore, short- and intermediate term MOEs are not a concern to primary handlers.

The similar MOE for the loaders/handlers adding ziram to paint during the manufacturing process at the maximum Vancide concentration (i.e., 0.5 percent) is estimated to be 250 when they make 1,000 gallon paint batches/day. Although both MOEs are sufficiently above the target MOE of 100, removal of some of the PPE is not recommended, as the CMA data do not accommodate exposure estimates for lower levels of PPE.

The occupational risk to commercial painters who apply exterior latex paint with airless sprayers while wearing long pants and long sleeved shirts is a concern (MOE is 30 *vs* target is 100). The risk when they apply paint with a brush is 170 (Table 15). These differences reflect the amount of paint that can be applied with a brush versus a sprayer.

Post-application Exposure From Antimicrobial Use

Dermal and inhalation postapplication exposures of ziram may occur in the industrial settings around open vats of processing material while maintaining industrial equipment. No exposure data are available to determine the extent of postapplication exposures in the industrial environment. However, dermal postapplication exposures are expected to be lower than exposures from handling product for manufacturing. Since the risks for use in manufacturing are below the Agency's level of concern, risks for postapplication exposures in industrial settings would also be below the level of concern. Similarly inhalation exposures are also expected to be minimal because of the low vapor pressure of ziram (1.4E-7 mm Hg at 25C) and no aerosols are formed while handling ziram. Postapplication dermal and inhalation exposures to commercial painters are also expected to be minimal because of the low vapor pressure of ziram and low dermal contact potential to the treated surfaces and/or adhesives. Therefore, postapplication exposures in the industrial setting is minimal and not of concern.

7. Human Incident Reports

The Agency has reviewed the OPP Incident Data System (IDS), the Poison Control Center (PCC), the California Department of Pesticide Regulation (CPDA) and the National Pesticide Telecommunications Network (NPTN) databases for reported incident information for ziram.

According to PCC and CPDA data, the majority of reported cases involved skin and eye irritation (e.g., skin rashes, conjunctivitis, and red, irritated, and itchy eyes and skin). Of the 23 PCC cases, 6 were non-occupational including one child under six years of age. A large proportion of cases resulted after field workers were exposed to ziram due to failure to wear, or the improper use of their PPE. Appropriate PPE such as the use of skin and eye protection would protect workers who may have extensive exposure to ziram. Only one non-occupational incident was reported by California from 1982 to 1999.

B. Ecological Exposure Assessment

A screening level ecological risk assessment was conducted for agricultural uses of ziram. Ziram was found to show low acute toxicity for mammals, is moderately toxic to avian

species and highly toxic to aquatic organisms. Exposure is determined by modeling residue concentrations on foodstuffs for terrestrial animals and in water for aquatic organisms. A summary of the Agency's environmental risk assessment is presented below. For a more detailed discussion of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division (EFED) Chapter, dated October 30, 2001, available in the public docket, and on the internet at www.epa.gov/pesticides.

The physical and chemical properties of ziram are summarized in the Chemical Overview in this document along in Chapter II C) with a list of breakdown products and their chemical names. The Use Sites applied in the environmental risk analysis is also provided in the Chapter II E.

1. Environmental Fate And Transport

The environmental fate database for ziram is essentially complete. The major routes of dissipation of ziram are hydrolysis, photodegradation and aerobic soil metabolism. Ziram's high susceptibility to degradation under neutral and acidic environments reduces residues of ziram significantly in soil and water, thereby minimizing the probability of prolonged exposure of terrestrial and aquatic organisms to the chemical.

The hydrolysis of ziram was found to be pH dependent with faster decomposition at the lower end of pH. At pH 5.0, almost all ziram was broken down into carbon disulfide (CS_2) in an hour and at pH 7.0, the production of CS_2 decreased to 81.6% in about 72 hours. At pH 9.0 the main degradate was carbonyl disulfide (COS). Under aqueous photolysis conditions, ziram yielded a first order half-life of 8.7 hours. About 15 degradates were identified in the photolysis study; however, the major degradates after 24 hours of irradiation were dimethyl formamide (DMF) at 23.7% and dimethylthioformamide (DMTF) at 18.1%. In contrast, under dark conditions ziram was relatively stable.

Soil studies indicate that ziram degraded by photolysis, and by microbial metabolism under aerobic and anaerobic conditions. In soil photodegradation tests, ziram degraded in less than one day under dark and light conditions. Among the 10 degradates isolated, the major breakdown product was thiram which also degraded rapidly. Under aerobic conditions in sandy loam soils, ziram dissipated with a half-life of 1.75 days, producing CO_2 and 1,1-dimethyl urea. In anaerobic soil, degradation was slower with a half-life of 14.1 days and yielded mainly CO_2.

No data are available on the bioconcentration of ziram in aquatic life, such as fish. However, based on the rapid degradation of ziram in water and soil, it is not expected to persist in water nor bind to soils; thus it would not accumulate in any significant amounts in aquatic plant and animal life.

The adsorption/desorption data indicated that ziram is moderately mobile in sandy, silt loam and sandy loam soils; but, shows low mobility in clay soils. The Freundlich coefficient for adsorption (K_{ads}) ranged from 2.9 to 7.6 and the organic carbon partition coefficient (K_{oc}) ranged from 314 to 1232 for sandy, silt loam and sandy loam soils. For clay soil the K_{ads} and K_{oc} were

68.1 and 3732, respectively. Volatilization of ziram is not expected to be a major route of dissipation due to its low vapor pressure (1.8×10^{-5} Pa at 25° C). The major degradates of ziram are CO_2, COS and CS_2, which are volatile and are not expected to persist in soil after their formation. Therefore, subsurface mobility of ziram is expected to be minimal.

Terrestrial field dissipation data indicate that the disappearance of ziram is biphasic in nature. Ziram 76 DF® Fungicide when applied by broadcast at 8 lb/acre/application, 9 times at 7 to 10 day intervals to bare ground plots of sand and sandy loam soils, dissipated from a depth of 0 to 3 inches in soil with a half-life of 6.7 days initially (0 to 10 days) followed by a half-life of 144 days (15 to 529 days). Following the 9th application, the parent compound was found at a maximum concentration of 8.3, 4.4, 1.2 and 0.24 ppm at 0 to 3 inches depth at 2, 7, 270 and 539 days, respectively. At a depth of 3 to 6 inches, the parent compound was found at a maximum concentration of 0.22 ppm at 8 hours and 0.18 ppm at 3 days post-treatment. The parent was not detected at a depth below 6 inches of soil.

2. Ecological Risk Level of Concern

Ecological risk characterization integrates the results of the assessment of exposure to ziram residues and ziram's acute/chronic toxicity to non-target organisms. In order to assess the potential for significant risk to nontarget organisms from the use of a pesticide, the Agency compares an estimated environmental concentration (EEC) to the appropriate toxicity effect level and develops a risk quotient (RQ). The RQ is the ratio of exposure concentration (EEC) to the toxicity level (RQ = Exposure/Toxicity). The Agency then compares the RQs to levels of concern (LOCs), which have been established for acute and chronic environmental risks. The risk presumptions and the corresponding LOCs established by the Agency are summarized in Table 16. When RQs exceed LOCs, the Agency may proceed with risk mitigation measures to reduce the risk to manageable levels.

Table 16. Risk Presumptions and Level of Concerns Used in the Terrestrial and Aquatic Risk Assessments.

Risk Presumption	LOC for Terrestrial Animals	LOC for Aquatic Animals
Acute High Risk: There is potential for acute risk; regulatory action may be warranted in addition to restricted use classification.	0.5	0.5
Acute Restricted Use: There is potential for acute risk; but, may be mitigated through restricted use classification.	0.2	0.1
Acute Endangered Species: There is potential for adverse effect to endangered species; regulatory action may warranted.	0.1	0.05
Chronic Risk: There is potential for chronic risk; regulatory action may be warranted.	1.0	1.0

3. Terrestrial Exposure Assessment

Residues of ziram and/or its degradates can find their way in terrestrial and aquatic environments when used as a pesticide for crop production or as an animal repellent by home owners.

Acute and chronic effects of exposure to ziram residues for birds and mammals that feed on plants (herbivores), insects (insectivores) and grain (grainivores) were estimated using surrogate data based on the nomogram developed by Hoerger and Kenaga (1972) and later modified by Fletcher (1994). Hoerger and Kenaga used a large set of field residue data, following application of liquid pesticide formulations (non-granular) applied to crop plants. The residue levels (EECs) deposited on off-target food plants of terrestrial animals were estimated to determine the upper limit values of EECs representing the 95th percentile. For this risk assessment, the Agency used FIFRA avian terrestrial exposure (FATE) model for multiple applications, incorporating the appropriate dissipation half-life numbers. The EECs thus generated are compared with ziram's toxicity to the respective animals (LD_{50} or LC_{50}) to arrive at the RQ for a particular use pattern.

a. Acute Risk to Birds

Ziram's toxicity to one of the avian species is provided below.

Table 17. Acute Toxicity of Ziram to Avian Species

Species	Type of Test	LD_{50} (mg/kg diet)	Toxicity Category
Mallard duck	Dietary	5156 MRID No. 423863-02	Moderately toxic

Ziram is moderately toxic to water fowl (Mallard duck) and upland game birds (Northern bobwhite quail) when tested as an acute oral exposure. It has low toxicity when mixed in the diet and fed in a subacute dietary basis. The chronic toxicity to the avian species has not been evaluated.

The acute effects to birds from exposures to ziram for various crop and geographical scenarios are summarized in Table 18.

Table 18. Acute Risk Quotients for Avian Species After Single Foliar Spray Application of Ziram

Crops	Max. Appln. Rate lb ai/A	Bird Habitats	Maximum EEC (ppm) [1]	Acute RQ [2]
Apricots, Cherries, Apples and Pears (Eastern) and Almonds, Pecans (Western)	6.1	Short grass	1464	0.30
		Seeds	92	0.02
Blueberries (Southern)	2.3	Short grass	552	0.12
		Seeds	35	0.00
Grapes, Tomato (Eastern)	3.0	Short grass	720	0.14
		Seeds	45	0.00

Peaches, Nectarines (Western)	7.6	Short grass	1824	0.35
		Seeds	114	0.02

Notes:
1. Maximum exposure concentrations (EECs) are based on Fletcher (1994).
2. RQs were calculated using LC_{50} value for Bobwhite quail = 5156 mg/kg diet. The risk presumptions are listed in Table 16.

The acute RQ values in Table 18 are based on use of ziram applied once a year on a variety of crops grown in Eastern, Southern and Western Geographic areas of the country with the sprays having a half-life of 35 days. The acute RQs are higher for all four use scenarios to birds that feed on short grass and in the acute restricted and endangered species list, as compared with birds that feed on seeds of plants. None of the use patterns are expected to have any significant risk to birds that are in the high acute risk list.

Table 19 represents the acute RQ values based on multiple applications of a non-granular formulation of ziram at the maximum single application rate with 1- or 35-day half-life for the residues and at the highest residue concentration after the last application (Fletcher, 1994).

Table 19. Acute Risk Quotients For Birds After Multiple Broadcast Foliar Applications of Ziram and at 1- and 35-Day Half-lives.

Crops (Region)	Appl Rate # Appls and Interval (days)	Bird Habitats	1-Day Half-life		35-Day Half-life	
			Max. EEC (ppm) [1]	Acute RQ [2]	Max. EEC (ppm)	Acute RQ
Apricots, Apples, Pears, Peaches, Cherries (Eastern USA)	6.1 lb ai/A 7, 7	Short grass	1476	0.30	7,024	1.0
		Seeds	92	0.02	439	0.09
Blueberries (Southern USA)	2.3 lb ai/A 2, 7	Short grass	556	0.12	1,033	0.20
		Seeds	35	0.00	65	0.01
Cherries (Western USA)	6.1 lb ai/A 4, 5	Short grass	1511	0.30	5,079	1.70
		Seeds	94	0.02	317	0.06
Grapes, Tomato (Eastern USA)	3.1 lb ai/A 7, 7	Short grass	726	0.14	7,024	0.70
		Seeds	45	0.01	216	0.04
Peaches, Nectarines (Western USA)	7.6 lb ai/A 6, 3	Short grass	2085	0.40	9,482	1.80
		Seeds	130	0.03	593	0.11

1. Maximum exposure concentrations (EECs) are based on Fletcher (1994).
2. RQs were calculated using LC_{50} value for Bobwhite quail = 5156 mg/kg diet. The risk presumptions are listed in Table 16.

With multiple applications, the restricted use LOCs for birds consuming shortgrass were exceeded as a result of application to pome fruits (Eastern U.S.) and stone fruits (Western U.S.). The RQs calculated with multiple applications and an average residue level for ziram after the last application (data not shown here), as compared with the highest residue concentration reported earlier, did not exceed the Agency's risk concern for birds with habitats on short grasses. The risk analyses also show that using the default 35-day half-life instead of ziram's 1 day half-life did not influence the outcome the RQ determination significantly.

b. Acute and Chronic Risk to Mammals

Ziram has low acute toxicity to mammals. The acute toxicity data available on mammalian species are provided below.

Table 20. Acute Toxicity of Ziram to Mammals

Species	Type of Test	LD_{50} /NOAEL	Toxicity Endpoint
Rat (*Rattus norvegicus*)	Acute oral	320 mg/kg (M/F) MRID No. 413404-01	Death
Rat *(R. norvegicus*)	2-Generation reproduction study	NOAEL = 207 mg/kg diet MRID No. 439358-01	Body weight loss and decreased food consumption

To assess the acute risk to terrestrial mammals (herbivores, insectivores and grainivores) from the use of ziram, RQs were calculated on a body weight basis using the rat acute oral LD_{50} as the end point. The estimated RQs for a single application of ziram exceeded the LOC for mammals that are herbivores and insectivores (Table 21). As expected, RQs estimated using variable inputs, such as multiple applications and 1- or 35-day half-lives of ziram also resulted in higher predicted risks to herbivores and insectivores.

Table 21. Acute Risk Quotients for Mammals After Single Foliar Spray Application of Ziram.

Site & Appl Rate	Body Wt (g)	Acute EEC (ppm) [1]		Acute RQ [2]	
		Short grass	Seeds	Herbi- & Insectivores	Graini-vores
Blue-berries 2.3 (lb ai/A) @2 appl. at 7 days interval	15	552	35	1.6	0.02
	35	552	35	1.1	0.2
	1000	552	35	0.3	0.00
Apricots, Apples (Eastern USA) 6.1 (lb ai/A)@ 5 appl. at 7 days interval	15	1464	92	4.3	0.06
	35	1464	92	3.0	0.04
	1000	1464	92	0.7	0.00
Peaches, Nectarines (Western USA), 7.6 (lb ai/A) @ 6 appl. at 3 days interval	15	1821	114	5.4	0.07
	35	1824	114	3.8	0.05
	1000	1824	114	0.9	0.01

1. Maximum exposure concentrations (EECs) are based on Fletcher (1994).
2. RQs were calculated using an acute oral LD_{50} value for rats = 320 mg/kg. The risk presumption are listed in Table 16.

To assess the chronic risk to terrestrial mammals from single and multiple foliar spray applications of ziram, RQs were calculated at a rat NOAEL of 207 ppm. The RQs calculated using a single application rate exceeded the LOC for herbivores at all sites. Multiple applications of ziram are projected to exceed the chronic RQs of herbivores and grainivores at all sites except blueberries in Southern United States (Table 21).

Table 22. Chronic Risk Quotients for Mammals After a Single or Multiple Foliar Spray Applications of Ziram.

Crops (Region) Appl Rate # of Applns and Interval	Food Items	Single Application		Multiple Applications	
		Max. EEC [1]	Chronic RQ [2]	Max. EEC [1]	Chronic RQ [2]
Blue-berries (Southern USA) 2.3 (lb ai/A) @2 appl. at 7 days interval	Short grass	552	2.67	1033	5.0
	Seeds	35	0.17	65	0.30

Apricots, Apples (Eastern USA) 6.1 (lb ai/A)@ 5 appl. at 7 days interval	Short grass	1464	7.10	7024	34.0
	Seeds	92	0.44	439	2.12
Peaches, Nectarines (Western USA), 7.6 (lb ai/A) @ 6 appl. at 3 days interval	Short grass	1824	8.80	9482	45.8
	Seeds	114	0.55	593	2.9

1 Maximum exposure concentrations (EECs) are based on Fletcher (1994).

2. Chronic RQs were calculated using an acute NOAEL for rats = 207 mg/kg. The risk presumption are listed in Table 16.

c. Risk to Insects

Currently, the Agency does not assess risk to nontarget terrestrial insects. Results of acceptable studies are used for recommending appropriate label precautions to mitigate any obvious risks. As Ziram is practically non-toxic (LD_{50} >100 μg/bee) to honeybees, low risk is assumed to other beneficial insects as well.

d. Terrestrial Ecological Incident Data

There are no reported ecological incidents for ziram in the Ecological Incident Information System (EIIS) database maintained by the Agency.

4. Risk to Aquatic Species

In this section, the effect of exposure of ziram to freshwater and estuarine/marine fishes and invertebrates and aquatic plants are discussed. Exposure to aquatic non-target organisms can occur from residues when ziram is used as an agricultural fungicide, antimicrobial preservative and from manufacturing waste. The major routes of entry into aquatic systems from agricultural uses are through surface water runoff, soil erosion, and off-target spray drift. To assess the risk to aquatic life, the Agency estimates an RQ, which is the ratio of EEC for ziram that can likely result in surface water and the acute or chronic toxicity of active ingredient to the representative aquatic organism. The EECs are based on use patterns of ziram and is a measure of potential exposure that can result from various uses. Details of how EECs are estimated are covered in the Dietary Exposure from Drinking Water section, under Human Health Risk Assessment Chapter.

a. Acute Exposure to Fish and Invertebrates

Table 23 summarizes the acute toxicity of ziram to aquatic life found in freshwater and estuarine/marine systems. Ziram is moderately to highly toxic to freshwater fish with a 96-hour LC_{50} ranging from 0.008 to 1.7 ppm and that for marine fish at 0.84 ppm. The acute toxicity to invertebrates, both freshwater and marine, is also high, ranging from 0.014 to 0.077 ppm. No data are available to assess the chronic toxicity effect of ziram to freshwater and/or marine organisms.

Table 23. Acute Toxicity of Ziram to Fish and Invertebrates from Freshwater and Marine Habitats.

Habitat	Species	Type of Test	LC_{50} or EC_{50} (mg/kg)	Toxicity Category
Freshwater Fish	Fathead minnow	96-hr	0.008 (MRID No. 05003523)	High
Freshwater Invertebrate	Daphnia Water flea	48-hr	0.048 (MRID No. 423863 -05)	High
Estuarine/Marine Fish	Sheepshead minnow	96-hr	0.84 (MRID No. 437816-01)	High
Estuarine/Marine Invertebrate	Mysid	96-hr	0.014 (MRID No. -01)	High

Table 24 below summarizes the RQs for freshwater and marine species from the use of ziram in five geographic locations.

Table 24: Acute Risk Quotients for Freshwater and Marine/Estuarine Fish and Invertebrates.

Crops (Region) Rate/Appln; # of Applns., Appln. Interval (days)	Peak EEC (mg/L) [1]	RQs of Freshwater Species [2]		RQs of Estuarine Species [3]	
		Fish	Inverteb.	Fish	Inverteb.
Blueberries (FL) 2.3 lb ai/A/appln. @ 4, 7	0.05	6.25	1.04	0.06	3.60
Cherries (WI) 6.1 lb ai/A/appln. @ 4, 7	0.027	3.38	0.50	0.03	2.00
Grapes (NY) 3.0 lb ai/A/appln. @ 7, 7	0.02	2.50	0.42	0.02	1.43
Peaches (OR) 7.6 lb ai/ A/appln @ 6, 3	0.03	3.75	0.63	0.04	2.14
Tomatoes (NJ) 3.0 lb ai/A/appln. @ 7, 7	0.03	3.75	0.60	0.04	2.14

1. Peak exposure concentration (EEC) for each crop was generated using PRZM/EXAMS.
2. RQ calculations are based on the Fathead minnow LC_{50} = 0.008 mg/L and Daphnid EC_{50} = 0.048 mg/L. The risk presumption are listed in Table 16.
3. RQ calculations are based on Sheepshead minnow LC_{50} = 0.84 mg/L and Mysid EC_{50} = 0.014 mg/L.

The RQs indicate that risk to freshwater fish is of concern as their acute RQs exceed the respective LOCs ($\geq$0.5) for all use patterns studied. The risks may be reduced by adopting certain mitigation measures but will not be eliminated. A similar analysis conducted on marine/estuarine fish reveals that they are not adversely affected. The chronic RQs for these aquatic organisms could not be estimated as no aquatic fish and invertebrate chronic toxicity data for ziram are available.

b. Toxicity and Risk to Aquatic Plants

Only limited data are available on the acute toxicity of ziram to aquatic plants. In one acute study, the phytotoxicity to *Selenastrum capricornutum* was reported to have an EC_{50} of 0.067 ppm. Additional studies are required to fully evaluate the potential for long term toxicity of ziram to aquatic plant life. Lacking additional data, no assessment of ziram's potential risk to aquatic plants are attempted at this time.

5. Endangered Species

The Agency's screening level risk assessment for Ziram concluded that there is a potential for risk to endangered species. The following is a revision and refinement of the original characterization of those risks.

Endangered Species

Endangered species LOCs for Ziram are exceeded for acute risk to herbivorous and insectivorous birds and mammals from single and multiple applications to pome fruits, stone fruits and nut crops as well as herbivorous birds and mammals plus insectivorous mammals from single and multiple applications to vegetable crops and grape. In addition the chronic LOC is exceeded for endangered mammals from single and multiple applications to all uses of Ziram. Exceeding the endangered species LOCs, suggests a potential concern for effects in listed species, should exposure actually occur.

Risks to endangered small mammals may be less than predicted in the assessment due to the possibility of aversion to eating treated food items. A registered label exists for the use of Ziram as a rabbit repellent. However, data is lacking to assess the efficacy of Ziram used as a rabbit repellent or whether repellency would occur across the spectrum of potentially exposed endangered mammalian species. Data from other mammalian dietary studies submitted to HED neither confirm nor refute aversion (R. Daiss, HED, pers. comm., 7/28/03). To further refine this risk concern and reduce uncertainty, additional data regarding mammalian aversion may be useful. In addition, in as much as this screening assessment incorporates generic assumptions of exposure, it does not address risks to specific endangered mammalian species. To reduce uncertainty with regard to risks to specific listed mammals, a more spatially and biologically specific assessment may be appropriate. Reductions in application rates and/or number of applications may also reduce overall risk to a certain degree. Risks to terrestrial organisms were mainly due to a combination of the compound's higher application rates, multiple applications and short intervals, rather than the compound's toxicity.

The EFED assessment also found a potential for adverse effects to endangered avian and aquatic species. The magnitude of the RQ's, even though exceeding the LOC's, were low. Acute LOCs for endangered freshwater fish and invertebrates, including mollusks and crustaceans, were exceeded for all uses of Ziram. Although the endangered species LOC for estuarine invertebrates has also been exceeded, there are no federally listed species in this group. Chronic risk to avian and aquatic species could not be sufficiently analyzed due to a lack of toxicity data. It is also not known if endangered plants may be affected due to a lack of toxicity

data. The chemical does appear to degrade quickly, thus reducing time of exposure. However, multiple applications on weekly intervals may affect organisms through chronic pulse doses. Based on the available avian data, there is also a potential for risk to endangered reptiles from the uses of Ziram.

This endangered species assessment will be refined using data that will be submitted as a result of this RED, in order to determine whether a species specific assessment needs to be conducted for avian, mammalian, aquatic and plant species.

6. Ecological Risk Characterization

Persistence in Soil and Water: Under neutral, acidic and aerobic environments, ziram is quickly broken down to volatile chemicals such as CS_2, CO_2, and COS. Ziram's susceptibility to degradation, especially in neutral and acidic environments, reduces the probability of prolonged exposure of wildlife to residues of ziram.

The degradation of ziram takes place mainly by hydrolysis. Some of the typical half-lives are: neutral to acidic conditions (0.17 to 151 hours), aqueous photolysis (8.7 hours), soil photolysis (8-9 hours) and anaerobic metabolism (14.1 days under anaerobic conditions). In addition, ziram degraded much faster under aerobic than anaerobic conditions during soil metabolism studies. The main degradates are volatiles such as CS_2, CO_2 and COS, and are not expected to persist in soil and water. However, in alkaline medium, ziram and its nonvolatile metabolites dimethyldithiocarbamic acid (DDC), N.N-dimethylformamide (DMF), and N.N-dimethylthioformamide (DMTF) are likely to be more persistent in soils or waters. The uncertainties related to the persistence of DDC, DMF, and DMTF could be a major concern for terrestrial and aquatic organisms of arid and semiarid regions. However, the toxicity of the degradates to organisms (terrestrial and aquatic) is unknown. It is unlikely that many aquatic organisms live under extremely high pH conditions, therefore exposure will likely be very limited.

Ziram may pose ecological risk to aquatic and terrestrial organisms through pulse dosing, due to the compound's high application rates and multiple applications at weekly intervals. The chemical can be leached in aquatic systems after rain events during the growing season and especially on days following application. Ziram's stability under arid conditions is also a concern under the heavy use conditions on peaches and nectarines in Western U.S.

Terrestrial Risk: The results of this assessment suggests that a potential for acute and chronic risk to mammals (other than grainivores) and acute risk to avian species from both single and multiple applications of ziram. The chronic risk to birds could not be assessed due to a lack of toxicity data.

EECs were calculated for terrestrial risk, using the default half-life of 35 days due to a lack of foliar data. The exposure estimates were also performed using an 1 day half-life for residues. Risks were of a greater magnitude using 35 days. However, taking the short intervals

(3-7 days) between applications into account, it is likely that ziram degrades enough during those intervals that efficacy would not be achieved without another application. Thus a shorter half-life than 35 days may be a more likely and realistic scenario. Nevertheless, even using 1 day half-life, LOCs were still exceeded. The results of a mammalian metabolism study in rats show that overall recoveries of administered radioactivity ranged from 78.9 to 92.4%, indicating rapid absorption in the gut followed by significant excretion of radioactivity via urine, expired air and feces with small amounts widely distributed throughout the body. Thus no tissue persistence is expected in exposed terrestrial animals even with high application rates of ziram on pome, nut trees, stone fruits and vegetables.

Aquatic Risk: Ziram's is a dimethyldithiocarbamate fungicide that is acutely highly toxic and poses high acute and chronic risk to the common aquatic organisms, should the compound enter aquatic habitats. Aquatic organisms were differentially sensitive to ziram. Freshwater fish (LC_{50} = 0.008 to 0.27 mg/L) were more sensitive than their estuarine counterparts (LC5 0.84 mg/L) by 3 orders of magnitude. However, the freshwater invertebrates are more tolerant (LC50= 0.048 mg/l) than their estuarine counterparts (LC50=0.014 mg/l).

Using a Tier II model (PRZM/EXAMS) for determining concentration of ziram in water, this assessment found certain degree of acute risk to freshwater fish, freshwater invertebrates and estuarine invertebrates. Although the parent is short lived, multiple applications on weekly intervals may affect aquatic organisms through chronic pulse doses, should the compound enter aquatic habitats. However, chronic risk to aquatic organisms could not be sufficiently analyzed due to a lack of toxicity data. In addition, since ziram is relatively highly soluble and is very highly toxic to aquatic organisms, there is a possibility of acute risk to amphibians through dermal exposure from broadcast spray applications.

IV. Risk Management, Reregistration, and Tolerance Reassessment

A. Determination of Reregistration Eligibility

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

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

Based on its evaluation of ziram, the Agency has determined that ziram 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 use of ziram. If all changes outlined in this document are incorporated into the product labels, then all current risks for ziram will be adequately mitigated for the purposes of this determination.

B. Public Comments and Responses

When making its reregistration decision, the Agency took into account all comments received after opening of the public docket. These comments in their entirety are available in the docket (OPP-34254). Comments on the risk assessment were submitted by one registrant, VJP Consulting, Inc. A formal Agency response to these comments can be found in the following document which is available in the public docket: “Response to Public Comments on the HED Risk Assessment for Ziram RED Chapter” dated January 18, 2002.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, the Agency has assessed the risks associated with ziram fungicide. The Agency has determined that the risk from dietary (food sources only) exposure is within the “risk cup.” In other words, the Agency has concluded that the tolerances for ziram meet the FQPA safety standards. In reaching this determination, the Agency has considered the available information on the special sensitivity of infants and children, as well as the acute and chronic food exposure to ziram. An aggregate assessment was conducted for exposures through food, drinking water, and residential uses as well. The Agency has determined that the human health risks from these combined exposures are within acceptable levels provided the mitigation outlined in this document occurs. Therefore, no changes in the ziram tolerances are required at this time due to risk concerns.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for ziram, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population from the use of ziram as specified. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and scenarios and the environmental behavior of ziram. As discussed in chapter 3, the total acute dietary (food alone) risk from ziram is below the level of concern as is the chronic (non-cancer) risk from food.

Although the projected surface water concentration marginally exceeds the Agency's level of concern for Children (1-6 years) age group, the Agency believes that those projections are conservative and may over-estimate the human exposure to ziram that may result from surface water. Except for the exceedance described above, exposure from drinking water is not a concern based on rate reductions and restricted aerial applications on certain agricultural crops. Risk from residential exposures to exterior latex paint is also not a concern based on rate reduction of ziram used in the paint as in-can preservative.

c. Determination of Safety to Infants and Children

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

In determining whether or not infants and children are particularly susceptible to toxic effects from ziram residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed and other information. A 3x FQPA safety factor was applied to the dietary and residential exposure assessment based on the following factors: (i) there is no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure to rats and rabbits and following pre- and postnatal exposure to rats in the standard developmental and reproduction studies with ziram; (ii) with respect to the data gaps identified in the toxicity database, the morphometric analysis of the submitted DNT study is outstanding; this data could confirm and characterize the effects seen with ziram; but, not increase the concern for the effects; and (iii) the dietary (food and drinking water) and residential exposure assessments will not underestimate the potential exposure for infants, children, and/or women of childbearing age. The 3x safety factor is required for all population subgroups when assessing dietary and residential exposures of all durations since

there is quantitative evidence of increased susceptibility in non-morphometric portion of the rat developmental neurotoxicity study.

d. Endocrine Disruptor Effects

The Agency 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), the Agency has determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. The Agency also adopted EDSTAC's recommendation that the Agency include evaluations of potential effects in wildlife. For pesticides, the Agency 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).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, ziram may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Effects

The Food Quality Protection Act (1996) stipulates that when determining the safety of a pesticide chemical, the Agency shall base its assessment of the risk posed by the pesticide chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

Ziram 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. While additional evaluation of possible cumulative effects of ziram and other substances that may have a common mechanism of toxicity is necessary, for the purposes of this risk assessment, EPA has assumed that ziram does not share a common mechanism of toxicity with other pesticides.

The Agency has recently developed a framework that it proposes to use for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance was issued for public comment on January 16, 2002 (67 FR 2210-2214) and is available from the OPP Website at
http://www.epa.gov/pesticides/trac/science/cumulative_guidance.pdf
In the guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed.

Before undertaking a cumulative risk assessment, the Agency will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the "*Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity*" (64 FR 5795-5796, February 5, 1999).

2. Residue Analytical Method

The enforcement methods (Pesticide Analytical Manual [PAM]) are based on the decomposition of dithiocarbamates with release of carbon disulfide (CS_2). The ziram residues of concern are expected to contain the CS_2 moiety, and can be determined by the analytical method. However, the analytical method cannot distinguish between ziram and ziram metabolites, nor can it distinguish between ziram and other thiocarbamates including ferbam, thiram, or the ethylenebisdithiocarbamates (EBDCs) which degrade to CS_2. The residue data are expressed in terms of ziram, per se. However, the tolerances currently are expressed in the form of zineb, but to harmonize with Codex it is proposed that they should be expressed in terms of CS_2.

3. Tolerances Summary

Tolerances for residues of ziram in/on raw agricultural commodities are currently expressed in terms of residues of ziram (zinc dimethyldithiocarbamate), calculated as zinc ethylenebisdithiocarbamate (zineb) [40 CFR §180.116]. Also, 40 CFR §180.3(d)(5) and 40 CFR §180.3(e)(3) which addresses tolerances on similar pesticides and specifically dithiocarbamates states as follows:

"Where tolerances are established for more than one member of the class of dithiocarbamates listed in paragraph (e)(3) of this section on the same raw agricultural commodity, the total residue of such pesticides shall not exceed that permitted by the highest tolerance established for any one member of the class, calculated as zinc ethylenebisdithiocarbamate."

The following pesticides are members of the class of dithiocarbamates: Metiram; §180.217, §180.319, Mancozeb; §180.176, §180.319, Ferbam {§180.114}, Maneb {§180.110}, Manganous dimethyldithiocarbamate {§180.161}, Sodium dimethyldithiocarbamate {§180.152}, Thiram {§180.132}, Ziram {§180.116}

The tolerances for ziram and the other dithiocarbamates are enforced by a common moiety method that determines carbon disulfide. The Agency is recommending that the tolerances for ziram and all other dithiocarbamates be changed to be expressed in terms of carbon disulfide. This recommended change in tolerance expression allows harmonization of US tolerances with Codex MRLs. This recommendation for a change in the tolerance expression should also apply to the other dithiocarbamate fungicides that are determined by the carbon disulfide common moiety method. This group includes ferbam, ziram, thiram, maneb, mancozeb, and metiram, which have current tolerances.

Consequently, in the interim, unless all the tolerances for dithiocarbamates can be changed simultaneously, it appears that in accordance with the above section it would be necessary to publish tolerances for ziram expressed as both zineb and carbon disulfide.

The listing of ziram tolerances under 40 CFR §180.116 should be subdivided into parts (a), (b), (c), and (d). Part (a) should be reserved for commodities with permanent tolerances, part (b) for Section 18 emergency exemptions, part (c) for tolerances with regional registrations, and part (d) for indirect or inadvertent residues.

Tolerances Listed Under 40 CFR § 180.116

Sufficient data have been submitted to reassess the established tolerances for the following commodities, as defined, pending label amendments for some crops: almonds, apples, apricots, blueberries, cherries, peaches, pears, and pecans. The tolerances for almonds, blueberries, peaches, and pecans are reassessed at the same level. The tolerances for apples, cherries, pears and tomatoes are reassessed at a decreased level, and the tolerance for apricots is reassessed at an increased level.

Insufficient data are available to ascertain the adequacy of the established tolerances for blackberries and grapes, or the need for tolerances in livestock commodities. Confirmatory data are being required for this purpose.

The tolerance for nectarines should be revoked as the tolerance for peaches is sufficient to address ziram residues in nectarines (40 CFR §180.1(h)). Several tolerances will be proposed for revocation by Federal Register notification because adequate data to support these tolerances have not been submitted to the Agency. The Federal Register notification is to allow any interested parties to inform the Agency of their intent to submit data in support of these tolerances.

Tolerances To Be Proposed Under 40 CFR §180.116

A tolerance is required for almond hulls (the registrant has already proposed this tolerance; see below).

Per OPPTS 860.1520 Guidelines, when residues in the processed food (i.e. concentration factor times highest average field trial) are significantly above the level of quantitation (LOQ), as the Agency rate tolerance will normally be needed if these residues are approximately 1.5x the tolerance for the raw agricultural commodity (or higher). Per OPPTS 860.1520 Guidelines when residues in the processed food commodity are 1.5x or higher than the tolerance for the raw agricultural commodity, a separate tolerance for that processed food commodity is required. Accordingly, tolerances for grape juice and apple pomace are not require (theoretical maximum for grape juice 1.2x and wet apple pomace 1.4x per apple processing study). However an appropriate tolerance for raisins reflecting the 2x concentration factor will be determined after all the grape field trial data have been submitted and reviewed.

Table 25. Tolerance Reassessment Summary for Ziram.

Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment & *[Correct Commodity Definition]***
Almonds	0.1	0.1	*[Almond, nutmeat]*
Apples	7	6	*[Apple]*
Apricots	7	20	[Apricot]
Beans	7	Propose revocation	
Beets, with or without tops	7	Propose revocation	
Beets, greens	7	Propose revocation	
Boysenberries	7	Propose revocation	
Brassica vegetable group	7	Propose revocation*	
Broccoli	7	Propose revocation	
Brussels sprouts	7	Propose revocation	
Cabbage	7	Propose revocation	
Carrots	7	Propose revocation	
Cauliflower	7	Propose revocation	
Celery	7	Propose revocation	
Cherries	7	6	*[Cherry, sweet]; [Cherry, tart]*
Collards	7	Propose revocation	
Cranberries	7	Propose revocation	
Cucumbers	7	Propose revocation	
Dewberries	7	Propose revocation	
Eggplants	7	Propose revocation	
Gooseberries	7	Propose revocation	
Kale	7	Propose revocation	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment & *[Correct Commodity Definition]*
Kohlrabi	7	Propose revocation	
Lettuce	7	Propose revocation*	
Loganberries	7	Propose revocation	
Melons	7	Propose revocation	
Nectarines	7	Propose revocation	Residues in/on nectarines are covered by the tolerance for peaches
Onions	7	Propose revocation	
Peaches	7	7	*[Peach]*
Peanuts	7	Propose revocation	
Pears	7	6	*[Pear]*
Peas	7	Propose revocation	
Pecans	0.1	0.1	*[Pecan]*
Peppers	7	Propose revocation**	
Pumpkins	7	Propose revocation	
Quinces	7	Propose revocation	
Raddish with or without tops	7	Propose revocation	
Raddish tops	7	Propose revocation	
Raspberries	7	Propose revocation	
Rutabaga with or without tops	7	Propose revocation	
Rutabaga tops	7	Propose revocation	
Spinach	7	Propose revocation	
Squash	7	Propose revocation	
Strawberries	7	Propose revocation	
Summer squash	7	Propose revocation	
Tomatoes	7	2	Use is limited to East of Rocky Mountains; *[Tomato]*
Turnip with or without tops	7	Propose revocation	
Turnip, greens	7	Propose revocation	
Young berries	7	Propose revocation	
Tolerance To Be Proposed Under 40 CFR § 180.116			
Almond, hulls	None	20	Tolerance petition pending
Apple, pomace, wet	None	TBD	Additional field trial data required
Blackberries	7	TBD	Additional data required; *[Blackberry]*
Blueberries	7	TBD	Additional data required;
Grapes	7	TBD	Additional field trials pending

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment & *[Correct Commodity Definition]*
Grape, juice	None	TBD	Additional field trial data required
Grape, raisin	None	TBD	Additional field trial data required

** IR-4 may be willing to support.
TBD To be determined

Codex Harmonization

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for ziram residues in/on various plant and animal commodities. Codex MRLs for ziram are currently expressed as carbon disulfide (CS_2). The Codex MRL residue definition and the U.S. tolerance definition are currently incompatible and will remain incompatible until the U.S. tolerance definition is revised to express in terms of CS_2. The Codex MRLs for dithiocarbamates and applicable U.S. tolerances for ziram recommendations are based on the conclusions drawn following reassessment of U.S. tolerances.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the current uses of ziram. The risk mitigation measures involve labeling changes as well as product cancellations which are set forth in the summary table of Section VI (Appendices) of this document.

1. Dietary (Food and Drinking Water) Risk Mitigation

The acute and chronic risks from consumption of ziram containing raw agricultural and processed commodities are below the Agency's level of concern. The acute risk from residues in drinking water are a concern for Children 1-6 years old, where the DWLOC was estimated to be 74 ppb as compared with an acute surface water EDWC of 98 ppb. However, the drinking water risk is considered to be within an acceptable range, because (i) of the conservative assumptions used in the models for estimating of EDWCs and (ii) the proposed cancellation of aerial applications and reduced single and/or seasonal applications of ziram are expected to further reduce the concentration of ziram that may be found in drinking water. Therefore, no further mitigation measures are being proposed at this time to address the marginal higher risk to Children (1-6 years old) from residues of ziram in drinking water. There is no acute risk from drinking water residues to any of the other population groups. The chronic risk from residues in drinking water is not a concern for all population sub groups.

2. Residential Handler Risk Mitigation

For home owners who apply ziram containing exterior latex paint with an airless sprayer, the short term MOE failed to meet the target MOE of 300. Applying 15 gallons of paint/day by an airless sprayer resulted in a MOE of 74 when using a paint product containing 3% ziram. The risk was at an acceptable level (above the target MOE of 300) if the concentration of ziram in the paint was lowered to a concentration of 1%. Therefore, in order for the use of ziram in exterior latex paint to be eligible for reregistration, the concentration must be lowered to 1%. Other paint products, such as textured paint, which is thicker and applied with a brush may continue to have ziram as a preservative at a concentration of 3%.

Home owners using the ziram formulation as a dust or as spray for repelling rabbits from ornamental plants around homes, result only in minimal exposures; therefore this exposure is not a concern.

3. Occupational Risk Mitigation

The main use of ziram is for the control of fungal diseases in agricultural crops and ornamental plants. A minor use is as an industrial preservative in exterior latex paints, sealants and caulking. Both agricultural and industrial biocide uses involve worker risks and require certain mitigation measures to manage the higher exposures.

Agricultural Uses: The highest occupational risk from ziram's use as an agricultural fungicide is to workers who mix liquid and wettable powder (WP) formulations and load them in aerial, air blast and ground boom spray equipment. The occupational risks to mixers/loaders, applicators and flaggers and the corresponding mitigation measures to manage the risk, if any, are summarized below:

- Mixer/loader risk
  - Liquid formulations: upgrade the personal protective equipment (PPE) from baseline (long pants, long sleeved shirts, no gloves, no respirators and open cabs) to minimal (long pants, long sleeved shirts, chemical resistant gloves, dust/mist respirators and open cabs) would provide adequate protection. The reduction in rate/application also is expected to further reduce exposure..
  - WP formulation: upgrading the PPE from baseline to maximum with engineering control would not adequately protect the workers. Packaging the WP formulations in water soluble bags is expected to reduce the exposure to satisfactory levels (MOE $\geq$ 580). The reduction in rate/application also is expected to further reduce exposure.

- Applicator/Flagger risk: just wearing baseline PPE, the risk is below the level of concern when working with any of the ziram formulations and any type of application equipment.

Post-Application Risk to Agricultural Workers: With respect to post application exposures of ziram in agricultural scenarios, the current REI of 48 hours was found to be adequate to protect the workers who re-enter the field to do farming operations ranging from low to high exposure activities.

Industrial Preservative Uses: Use of Vancide MZ-96 (EPA Reg. No. 1965-79) as an industrial preservative in paints, caulking, adhesives and sealants results in exposure to primary and secondary handlers. Primary handlers are those workers who add the Vancide product to the paint and other materials at the manufacturing stage and the secondary handlers are those workers who handle or work with the products to which ziram has been incorporated. The Agency's short and intermediate term risk analyses indicate that the exposure to primary handlers is not a concern. However, secondary handlers who are commercial painters are at risk when they use an airless sprayer to apply exterior latex paint containing ziram at a concentration of 3%. This risk can be mitigated by lowering the concentration of ziram in exterior latex paint to 1%. The Agency's exposure assessment was based on a professional painter using 50 gallons of paint per day, and the homeowner using 15 gallons of paint per day. Based on these exposure scenarios, both professional and homeowner painters exceeded the Agency's level of concern. Therefore, in order for the use of ziram in exterior latex paint to be eligible for reregistration, the concentration must be lowered to 1%.

4. Environmental Risk Mitigation

Although ziram is not-persistent in nature and has a half-life of 0.17 to 42 hours in the environment, there are potential risk of concern to ecosystems. The estimated RQs for the ecological organisms exceed the levels of concern for aquatic, avian and mammalian species.

To mitigate the potential ecological risks, adopting the following measures should lower the risks to aquatic and terrestrial organisms.

- Rate reductions on apples, pears, Eastern cherries, and Western peaches/nectarines.
- Reduction in the number of applications to peaches/nectarines, apricots, cherries and pecans.
- Cancellation of aerial applications on Eastern apples and pears, Eastern cherries, Eastern peaches and nectarines, pecans, blackberries, blueberries, tomatoes, and Eastern grown grapes.

The proposed mitigation measures are summarized in Table 26 on the following page.

Table 26. Proposed Label Changes on Major Crops to Mitigate Ecological Risks of Ziram.

Crop	current			proposed			Comments
	ai lb/A per appl.	# of app	ai lb/A, Max rate/season	ai lb/A per appl.	# of app	ai lb/A, Max rate/season	
Almonds	6.1	4	24.4	No change			
Apples/Pears (East)*	6.1	7	42.7	4.6	7	32.2	Rate reduction Aerial application cancelled
Apples/Pears (West)*	6.1	4	24.4	4.6	4	18.4	Rate reduction Aerial application used preharvest only
Apricots	6.1	5	30.5	6.1	4	24.4	Reduced number of applications
Cherries (East)	6.1	5	30.5	4.6	4	18.4	Reduced rate and number of applications Aerial application cancelled
Cherries (West except CA)	4.6	5	23.0	4.6	4	18.4	Reduced number of application
Cherries California	3.8	6	22.8	3.8	4	15.2	Reduced number of application
Peaches/ Nectarines (East)	6.1	9	54.9	6.1	6	36.6	Reduced number of applications Aerial application cancelled
Peaches/ Nectarines (West)	6.1	9	54.9	4.6	6	27.6	For brown rot, blossom blight, twig blight, fruit rot, peach blight
Peaches/ Nectarines (Western US for leaf curl)	7.6	7	53.2	7.6	6	45.6	For leaf curl
Pecans	6.1	8	48.8	6.1	6	36.6	Reduced number of applications Aerial application cancelled
Blackberries	2.3	1	2.3	No change			Aerial application cancelled
Blueberries	2.3	2	4.6	No change			Aerial application cancelled
Tomatoes	3.0	6	18.0	No change			Aerial application cancelled
Grapes (East)	3.0	7	21.0	No change			Aerial application cancelled

* East denotes crops grown east of the Rocky Mountains, West denotes crops grown to the west of the Rockies. No specification is for crops grown anywhere in the US.

Additionally, for crops and areas where aerial use is retained, the Ziram Task Force has proposed language to specify "Aerial application may only be used when ground equipment (air-blast) cannot be used." The EPA is not planning to require this language, but does not object to the inclusion of the statement on the label.

No further mitigation is proposed at this time. Considering the seasonal rate reductions and some conservative assumptions used in the assessment models (highest rates with multiple applications) the risks to non-target organisms are considered to be within an acceptable range.

5. Other Labeling Requirements

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

6. Endangered Species

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. EPA is not requiring specific label language at the present time relative to threatened and endangered species. The general risk mitigation required through this RED will serve to protect listed species of potential concern until such time as the agency refines its risk assessment for birds, mammals, aquatic species and plants from the uses of ziram. 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.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. These Pamphlets are available for voluntary use by pesticide applicators, on the Agency's web site at *www.theAgency.gov/espp* A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the Federal Register on December 2, 2002.

V. What Registrants Need To Do

In order to be eligible for reregistration, all registrants of ziram are required to implement the label changes outlined in Chapter V by submitting amended labels. The label changes in Chapter IV involve occupation and ecological risk mitigation measures and that in Chapter V cover sites eligible for reregistration and related changes.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the registration of ziram for the eligible uses has been reviewed and determined to be substantially complete. The outstanding or confirmatory data are required to complete the generic data base and/or refine the dietary, occupational and ecological risk assessments. These studies are listed below:

Product Chemistry

- 830.7840 Additional water solubility studies using column elution or shake flask method
- 830.1750 Certification of Limits
- 830.1620 Description of Production Process
- 830.7050 UV/Visible Absorption

Environmental Fate

- 835.4100 Aerobic soil metabolism with one soil type near neutral pH
- 835.6100 Terrestrial field dissipation - upgrade existing study or submit new study

Ecological Effects

- 850.1300 Chronic toxicity study for freshwater aquatic invertebrates
- 850.1350 Chronic toxicity study for estuarine/marine aquatic invertebrates
- 850.1400 Early Life Stage Freshwater Fish
- 850.1450 Early Life Stage Estuarine Fish
- 850.1500 Fish life cycle study for freshwater and estuarine/marine fish
- 850.2300 Avian reproduction with mallard duck
- 850.4225 Seedling Germination and Seedling Emergence
- 850.4250 Vegetative Vigor
- 850.4400 Aquatic plant toxicity study (Tier 2)

Residue Chemistry

- 860.1300 Nature of residue - plants, livestock and processed food/feed commodities
- 860.1500 Additional residue data required for blackberries, blueberries, grapes, and tomatoes

- 860.1540 Additional reduction of residue data for orchard fruits, including washing and processing studies (cooking data suggested)

Toxicology

- 870.3465 90-day Inhalation Study in Rats
- 870.5395 In Vitro Mammalian Cytogenetics Tests
- 870.6300 Developmental Neurotoxicity Study
- 870.7485 Metabolism and Pharmacokinetics

Details of the data requirements can be obtained from: HED Risk Assessment for the RED Document dated February 10, 2003 on Residue and Product Chemistry and Toxicology studies and EFED Chapter for Ziram dated October 30, 2001on Environmental Fate and Eco Tox studies.

2. Labeling for Technical and Manufacturing-Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 27: Labeling Changes Summary Table.

B. End-Use Products

1. Additional Product Specific Data Requirements

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

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 27: Labeling Changes Summary Table. In order to be eligible for reregistration, all technical, manufacturing-use and end-use product labels have to be amended to incorporate the risk mitigation measures outlined in Chapter 4. Table 27 describes how statements on the labels have to amended. For more information on placement of various sections and required type sizes, see the Label Review Manual.

C. Label Changes Summary Table

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

Table 27: Summary of Labeling Changes for Ziram

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
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	"Only for formulation into a fungicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Formulation of Wettable Powder Products for Agricultural or Ornamental Use	Products that contain directions for use on agricultural or ornamental crops must be packaged in water soluble packaging.	Directions for Use

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
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 Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wash waters."	Directions for Use
Products used as Industrial Preservatives	To be eligible for reregistration, the concentration of ziram in latex paints must be lowered to 1percent by weight.	

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED for Liquid Formulations[1]	"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 handlers must wear: -Long-sleeved shirt, long pants, and -Shoes plus socks. In addition mixers, loaders, and cleaners of equipment must wear: -Chemical resistant gloves, such as (*registrant insert correct chemical-resistant materials).* See Engineering Controls for additional requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
PPE Requirements Established by the RED for Wettable Powder Formulations, except products solely labeled for use by homeowners for rabbit control or products solely labeled for use as an industrial preservative[1] *Wettable Powder products labeled for use on agricultural or ornamental crops must be packaged in water soluble bags to be eligible for reregistration.*	"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 handlers must wear: -Long-sleeved shirt and long pants, and -Shoes plus socks. In addition, mixers, loaders, and cleaners of equipment must wear: -Chemical-resistant gloves, such as *(registrant insert correct chemical-resistant materials),* and -A chemical resistant apron. See engineering controls for additional requirements.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
PPE Requirements Established by the RED for Wettable Powder Formulations labeled for use as an industrial preservative	"Personal Protective Equipment (PPE)" Some materials that are chemical-resistant to this product are" (*registrant insert 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 handlers must wear: -Long-sleeved shirt and long pants, and -Shoes plus socks -Chemical resistant gloves such as (*registrant insert correct chemical-resistant material*), -A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21 *or* a NIOSH-approved respirator with any N, R, P, or HE filter."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED for Dry Flowable Formulations [1]	"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-resistant category selection chart. All handlers must wear: -Long-sleeved shirt and long pants, and -Shoes plus socks." See engineering controls for additional requirements.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
PPE Requirements Established by the RED for Wettable Powder Formulations, except products solely labeled for use by homeowners for rabbit control or products solely labeled for use as an industrial preservative [1] *Wettable Powder products labeled for use on agricultural or ornamental crops must be packaged in water soluble bags to be eligible for reregistration.*	Engineering Controls "Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must : -- wear the personal protective equipment required above for mixers/ loaders, and -- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH-approved respirator with any N, R, P, or HE filter." "Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
Engineering Controls for Liquid and Dry Flowable Formulations	"Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
Environmental Hazards	For end-use products containing directions for use on agricultural crops and ornamentals: "This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from target area. Do not contaminate water when disposing of equipment washwater." For end-use products containing directions for use as an industrial preservative: "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 Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wash waters."	Precautionary Statements immediately following the User Safety Recommendations

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
Restricted-Entry Interval for all end-use products with uses within the scope of the Worker Protection Standard for Agricultural Pesticides	"Do not enter or allow worker entry into treated areas during the restricted entry interval of 48 hours."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment established by the RED for all end-use products with uses within the scope of the Worker Protection Standard for Agricultural Pesticides	"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, - chemical-resistant gloves made of any waterproof material, - shoes plus socks, and - protective eyewear."	
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.

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
Entry Restriction for all end-use products with ornamental uses not within the scope of the Worker Protection Standard for Agricultural Pesticides	Liquids: "Do not allow people or pets to enter the treated area until sprays have dried." Dry formulations: "Do not allow people or pets to enter the treated area until dusts have settled.	Direction for Use under the heading "General Precautions and Restrictions"

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions (Note: the maximum allowable application rate and maximum allowable rate per crop cycle 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: <u>Apples/pears (East of the Rockies)</u>: -maximum allowable rate per application of 4.6 lbs ai/A -maximum allowable rate per crop cycle is 32.2 lbs ai/A -maximum applications per crop cycle is 7 -aerial application is prohibited <u>Apples/Pears (West of the Rockies):</u> -maximum allowable rater per application of 4.6 lbs ai/A -maximum allowable rate per crop cycle is 18.4 lbs ai/A -maximum applications per crop cycle is 4 -aerial application allowed only as a preharvest application <u>Apricots:</u> -maximum allowable rate per application is 6.1 lbs ai/A -maximum allowable rate per crop cycle is 24.4 lbs ai/A -maximum applications per crop cycle is 4 <u>Cherries (East of the Rockies):</u> -maximum allowable rater per application of 4.6 lbs ai/A -maximum allowable rate per crop cycle is 18.4 lbs ai/A -maximum applications per crop cycle is 4	Place in the Directions for Use under Application Instructions for Each Crop

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions (continued) (Note: the maximum allowable application rate and maximum allowable rate per crop cycle must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	<u>Cherries (CA only):</u> -maximum allowable rate per application is 3.8 lbs ai/A -maximum allowable rate per crop cycle is 15.2 lbs ai/A -maximum applications per crop cycle is 4 <u>Cherries (West of the Rockies, except CA):</u> -maximum allowable rate per application is 4.6 lbs ai/A -maximum allowable rate per crop cycle is 18.4 lbs ai/A -maximum applications per crop cycle is 4 <u>Peaches/Nectarines (East of the Rockies):</u> -maximum allowable rate per application is 6.1 lbs ai/A -maximum allowable rate per crop cycle is 36.6 lbs ai/A -maximum applications per crop cycle is 6 -aerial application is prohibited Peaches/Nectarines (West of the Rockies): <u>For brown rot, blossom blight, twig blight, fruit rot, peach blight:</u> -maximum allowable application rate is 4.6 lbs ai/A -maximum allowable rate per crop cycle is 27.6 lbs ai/A -maximum applications per crop cycle is 6	Place in the Directions for Use under Application Instructions for Each Crop

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions (continued) (Note: the maximum allowable application rate and maximum allowable rate per crop cycle must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	Peaches/Nectarines (West of the Rockies): For leaf curl: -maximum allowable application rate is 7.6 lbs ai/A -maximum allowable rate per crop cycle of 45.6 lbs ai/A -maximum applications per crop cycle is 6 Pecans: -maximum allowable application rate is 6.1 lbs ai/A -maximum allowable rate per crop cycle is 36.6 lbs ai/A -maximum applications per crop cycle is 6 -aerial application is prohibited Blackberries, Blueberries, Tomatoes, Grapes (East of the Rockies): -aerial application is prohibited The following crops must be deleted from labels: Beans, Beets, Boysenberries, Broccoli, Brussel Sprouts, Cabbage, Carrots, Cauliflower, Celery, Collards, Cranberries, Cucumbers, Dewberries, Eggplants, Gooseberries, Kale, Kohlrabi, Lettuce, Loganberries, Melons, Onions, Peanuts, Peas, Peppers, Pumpkins, Quinces, Radish, Raspberries, Rutabaga, Spinach, Summer Squash, Strawberries, Turnip, Young berries.	Place in the Directions for Use under Application Instructions for Each Crop

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions for End-Use Products with Industrial Preservative Uses	Maximum concentration in latex paint is limited to one percent active ingredient by weight. Maximum concentration in all other paints is limited to three percent active ingredient by weight.	Directions for Use
Spray Drift	The Agency is currently working with stakeholders to develop appropriate label statements to address spray drift risk. Once this process has been completed, ziram product labels will need to be revised to include this additional language.	Directions for Use

Table 27: Summary of Labeling Changes for Ziram		
Description	**Amended Labeling Language**	**Placement on Label**
End Use Products Intended Primarily for Use by Homeowners		
Application Restrictions	"Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restriction	"If applied as a spray, do not allow people or pets to enter the treated area until sprays have dried." "If applied as a dust, do not allow people or pets to enter the treated area until dusts have settled.	Directions for Use under General Precautions and Restrictions

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

[2] If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 24 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; *Federal Register*, Volume 56, No. 123, June 26, 1991.

VI. Appendices

Appendix A. Food/Feed Use Patterns Subject To Reregistration For Ziram

Site Application Type[1] Application Timing Application Equipment	Max. Single Application Rate (ai/Acre)	Max. Number of Applications.	Maximum Rate (ai/Acre/Season)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (PHI)	Use Limitations [d]
Almonds (nutmeat, hulls)						
Delayed dormant (prebloom) and foliar, ground or aerial	6.1	4	24.4	3[1]	NS	Applications may be made at popcorn, full bloom, petal fall, or as needed.
	6.1	4	24.4	3[2]	NS	Applications may be made from prebloom through petal fall periods. Applications later than 5 weeks after petal fall are prohibited.
Apples/Pears (Eastern US)						
Delayed dormant (prebloom) and foliar, ground or aerial	4.6	7	32.2	7	14	Applications may be made from prebloom through cover sprays as needed.
Apples/Pears (Western US)						
Delayed dormant (prebloom) and foliar, ground or aerial	4.6	4	18.4	10	14	Applications may be made from prebloom through cover sprays as needed.
Apricots						
Delayed dormant (prebloom) and foliar, ground or aerial	6.1	4	24.4	7	30	Application may be made at prebloom, bloom, and petal fall through early cover sprays.
	4.6	5	22.8	7	30	Applications may be made at popcorn, full bloom, petal fall, and/or 5 weeks after petal, and in cover sprays as needed.
Blackberries						
Foliar, ground or aerial	2.3	1	2.3	NS	NS	Use in CA is prohibited. A single application may be made between mid-June and early July.
Blueberries						
Foliar, ground or aerial	2.3	2	4.6	7	NS	Use in CA is prohibited. Applications may be made at loose bud scale stage and 7 days later. Application later than 3 weeks after bloom is prohibited.

Site Application Type[1] Application Timing Application Equipment	Max. Single Application Rate (ai/Acre)	Max. Number of Applications.	Maximum Rate (ai/Acre/Season)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (PHI)	Use Limitations [d]
Delayed dormant, foliar, ground or aerial	3.0	NS	15.2	7	14	Use limited to MI and NJ. Applications may be made beginning at bud break (green tip) or when conditions for disease development exist.
Cherries (Eastern US)						
Delayed dormant (prebloom) and foliar, ground or aerial	4.6	4	18.4	7	14	NS
Cherries (Western US)						
	4.6	4	18.4	5	NS	Use limited to western U.S. except CA. Applications may be made at pre bloom, bloom, petal fall, and shuck stages, and approximately 2 weeks after shuck fall.
Cherries (California)						
Delayed dormant (prebloom) and foliar, ground or aerial	3.8	4	15.2	5	7	Use limited to CA. Applications may be made at prebloom, bloom, petal fall, and shuck stages, and approximately 2 weeks after shuck fall.
Grapes (Eastern)						
Foliar, ground or aerial	3.0	7	21.0	7	21	Use limited to eastern U.S. (east of the Rockies). Applications may be made beginning when shoots are at least one inch long and continue at 7- 14 day intervals or as necessary.
	3.0	NS	NS	NS	10	Use limited to western U.S. (west of the Rockies). Applications may be made beginning when shoots are 0.5 to 1.5 inches long and repeated at 7 to 10 day intervals as needed. Application after bloom is prohibited.

Site Application Type[1] Application Timing Application Equipment	Max. Single Application Rate (ai/Acre)	Max. Number of Applications.	Maximum Rate (ai/Acre/Season)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (PHI)	Use Limitations [d]
Foliar, ground or aerial	3.0	NS	NS	NS	NS	Use limited to western U.S. (west of the Rockies). Applications may be made before bud swell and repeated after blossoming but before fruit forms. Application after bloom is prohibited.
Peaches/Nectarines (Eastern US)						
Delayed dormant (prebloom), dormant, ground or aerial, and foliar, ground or aerial	6.1	6	36.6	7	14	
Peaches/Nectarines (Western US)						
Delayed dormant (prebloom), dormant, ground or aerial, and foliar, ground or aerial	4.6	6	27.6	3[1]	30	.
Peaches/Nectarines (Western US for leaf curl)						
Delayed dormant (prebloom), dormant, ground or aerial, and foliar, ground or aerial	7.6	6	45.6	7	NS	
Pecans						
Foliar, ground or aerial	6.1	6	36.6	14	NS	
Tomatoes						
Foliar, ground or aerial	3.0	6	18.0	7	NS	

1. Allowed only under very warm humid conditions. Re-treatment will generally occur on a longer interval.

2. Formulation represented are dry flowable (Ziram 76DF), liquid flowable (Ziram 4L) and wettable powder (Ziram 76WP)

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

REQUIREMENT			CITATION(S)
New Guideline Number	Old Guideline Number	Description	
PRODUCT CHEMISTRY			
830.1550	61-1	Product Identity and Composition	44610401, 41341001
830.1600	61-2	Starting Materials & Manufacturing Process	44610401, 41341001
830.1620	61-2A	Description of Production Process	**DATA GAP**
830.1670	61-2B	Formation of Impurities	44610401, 41341001, 40962201
830.1700	62-1	Preliminary Analysis	44856802, 41341002
830.1750	62-2	Certification of Limits	41341002, 43736301, **DATA GAP**[1]
830.1800	62-3	Analytical Method	44723301, 41341002
830.6302	63-2	Color	44856801, 41341003, 40348501
830.6303	63-3	Physical State	44856801, 40348501
830.6304	63-4	Odor	44856801, 41341003, 40348501
830.6313	63-13	Stability	44856801, 41341003, 40348501, 42601401
830.7000	63-12	pH	44856801, 41341003, 40348501
830.7050	None	UV/Visable Absorption	44856801, **DATA GAP**
830.7200	63-5	Melting Point	44856801, 41341003, 40348501
830.7300	63-7	Density	44856801, 41341003, 40348501, 42555401
830.7370	63-10	Dissociation Constant	44856801, 41341003, 40348501
830.7550	63-11	Octanol/Water Partition Coefficient	44856801, 41341003, 00258212, 40348501
830.7840	63-8	Solubility	42503501, **DATA GAP**
830.7950	63-9	Vapor Pressure	44856801, 00259218, 40348501
ECOLOGICAL EFFECTS			
850.2100	71-1A 71-1B	Avian Acute Oral Toxicity	41725701, 42386302
850.2200	71-2A	Avian Dietary Toxicity - Quail	42386301, 42386302
850.2200	71-2B	Avian Dietary Toxicity - Duck	42386301

REQUIREMENT			CITATION(S)
New Guideline Number	Old Guideline Number	Description	
850.2300	71-4A	Avian Reproduction - Quail	**DATA GAP**
850.2300	71-4B	Avian Reproduction - Duck	**DATA GAP**
850.1075	72-1A	Fish Acute Toxicity Bluegill	42386303
850.1075	72-1C	Fish Acute Toxicity Rainbow Trout	42386304
850.1010	72-2	Invertebrate Toxicity	42386305
None	72-3A	Estuarine/Marine Toxicity - Fish	43781601
None	72-3B	Estuarine/Marine Toxicity - Mollusk	43781602
None	72-3C	Estuarine/Marine Toxicity - Shrimp	43781603
850.1350	72-4A	Fish- Early Life Stage - Daphnid	**RESERVED**
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	**RESERVED**
850.1400	72-4C	Estuarine Invertebrate Life-Cycle-Freshwater Fish	**DATA GAP**
850.1450	72-4D	Early Life Stage Estuarine Fish	**DATA GAP**
850.1500	72-5	Life Cycle Fish	**DATA GAP**
850.4225	123-1A	Seed germ/seedling emergence	**RESERVED**
850.4250	123-1B	Vegetative vigor	**RESERVED**
850.4400	123-2A	Aquatic Plant Toxicity Test, Tier 1	43833901, **PARTIAL**
850.4400	123-2B	Aquatic Plant Toxicity Test, Tier 2	**DATA GAP**
850.3020	141-1	Honey Bee Acute Contact	41667901
TOXICOLOGY			
870.1100	81-1	Acute Oral Toxicity-Rat	41340401, 42429301, 43701301
870.1200	81-2	Acute Dermal Toxicity-Rabbit	41340402
870.1300	81-3	Acute Inhalation Toxicity-Rat	41442001
870.2400	81-4	Primary Eye Irritation-Rabbit	41643001, 41454401
870.2500	81-5	Primary Skin Irritation	41643002, 41454602
870.2600	81-6	Dermal Sensitization	41643003
870.6200	81-8	Neurotoxicity Screening Battery	43362801
870.6200	82-7	Subchronic Neurotoxicity Screening Battery	43413701
870.3100	82-1A	90-Day Oral Toxicity - Rodent	42450301
870.3200	82-2	21-Day Dermal Toxicity- Rabbit	41297001

REQUIREMENT			CITATION(S)
New Guideline Number	Old Guideline Number	Description	
870.3465	82-4	90-Day Inhalation-Rat	**DATA GAP**
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	43404201, 45770201
870.4100	83-1B	Chronic Feeding Toxicity - Dog	42823901
870.4200	83-2A	Oncogenicity - Rat	43404201, 45770201
870.4200	83-2B	Oncogenicity - Mouse	43373701
870.3700	83-3A	Developmental Toxicity - Rat	41908701
870.3700	83-3B	Developmental Toxicity - Rabbit	00161316
870.3800	83-4	2-Generation Reproduction - Rat	43935801
870.5265	84-2	Gene Mutation	00147462, 41642901
870.5300	84-2	Gene Mutation- Mammalian Cell	45806501
870.5375	84-2B	Structural Chromosomal Aberration (Cytogenetics)	41287802, 45522001
870.5395	84-2	Erythrocite micronucleus Test-mamalian	**DATA GAP**
870.5550	84-2	Bacterial DNA Damage or Repair	41287801
870.6300	83-6	Developmental Neurotoxicity - Rat	43935801, **DATA GAP**
870.7485	85-1	Metabolism and Pharmacokinetics	42391001, 42391002, **DATA GAP**
870.7600	85-2	Dermal Absorption- Rat	41297001
ENVIRONMENTAL FATE			
835.2120	161-1	Hydrolysis	43866701
835.2240	161-2	Photodegradation - Water	44097701
835.2410	161-3	Photodegradation - Soil	43642501, 44228401
835.4100	162-1	Aerobic Soil Metabolism	43985801, **DATA GAP**
835.4200	162-2	Anaerobic Soil Metabolism	44228402
835.1240	163-1	Leaching/Adsorption/Desorption	43873501
835.6100	164-1	Terrestrial Field Dissipation	44548301, 44548302, **DATA GAP**

REQUIREMENT			CITATION(S)
New Guideline Number	Old Guideline Number	Description	
RESIDUE CHEMISTRY			
860.1300	171-4A	Nature of Residue - Plants, livestock, and processed food/feed commodities	**DATA GAP**
860.1300	171-4B	Nature of Residue - Livestock	**DATA GAP**
860.1500	171-4K	Crop Field Trials (Blackberries)	**DATA GAP**
860.1500	171-4K	Crop Field Trials (Blueberries)	**DATA GAP**
860.1500	171-4K	Crop Field Trials (Grapes)	**DATA GAP**
860.1500	171-4K	Crop Field Trials (Tomatoes)	**DATA GAP**
860.1540	171-5	Anticipated Residues	**DATA GAP**

N/A not applicable

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 Bell St., Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30am to 4pm.

The docket initially contained preliminary risk assessments and related documents as of March 27, 2002. 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 ???.

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/op

These documents include:

HED Documents:

1. Daiss, Rebecca (USEPA/OPPTS/OPP/HED). HED RED Chapter for Ziram. January 2002.
2. Daiss, Rebecca (USEPA/OPPTS/OPP/HED). Revised HED RED Chapter for Ziram. February 2003.

EFED Documents:

1. Federoff, Nicholas (USEPA/OPPTS/OPP/EFED). Revised EFED RED Chapter for Ziram. October 2001.
2. Khan, Faruque (USEPA/OPPTS/OPP/EFED). Revised Tier II Surface Drinking Water Assessment for Human Health. January 2002.

Other Documents:

1. Dobak, Patrick (USEPA/OPPTS/OPP/SRRD). Overview of Ziram Risk Assessment. February 2002.
2. Dobak, Patrick (USEPA/OPPTS/OPP/SRRD). Risk Assessment Executive Summary. February 2002.

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

GUIDE TO APPENDIX D

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence

contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

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

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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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 separate cover.

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

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

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

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

registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Eighteen products were found which contain **Ziram** as the active ingredient. These products have been placed into four batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation.

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

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

Batch 1	EPA Reg. No.	% Active Ingredient
	1965-79	96.0
	1965-88	96.0
	4581-261	98.0
	45728-14	98.0

Batch 2	EPA Reg. No.	% Active Ingredient
	10163-90	87.3
	10163-129	87.3

Batch 3	EPA Reg. No.	% Active Ingredient
	10163-106	76.0
	10163-151	76.0
	19713-68	76.0
	19713-279	76.0
	34704-67	76.0
	34704-471	76.0

Batch 4	EPA Reg. No.	% Active Ingredient
	19713-93	39.2
	19713-270	39.2

No Batch	EPA Reg. No.	% Active Ingredient
	4-403	23.0
	4581-140	76.0
	10163-74	76.0
	45728-12	76.0

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

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

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

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

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

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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

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

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

   Date of receipt
   EPA identifying number
   Product Manager assignment

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

   To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the

chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

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

1. Environmental Fate and Effects Division Chapter.
2. Revised Health Effects Division Chapter.