United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

~~EPA 738-R-06-007~~
September 2006

Reregistration Eligibility Decision for Pine Oil (Case 3113)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 risk assessments for the antimicrobial pine oil. The Reregistration Eligibility Decision (RED) was approved in the form of a decision memorandum which summarized the regulatory decision for pine oil on September 30, 2004. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for pine oil and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for pine oil are available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2004-0302 at: http://www.regulations.gov.

The pine oil RED was developed through EPA's public participation process, published in the Federal Register on July 20, 2005, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the pine oil risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to pine oil alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants

at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that pine oil 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. Sections IV and V of this RED document 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 document.

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 pine oil. 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 label changes necessary for reregistration, please contact the Chemical Review Manager, ShaRon Carlisle, at (703) 308-6427. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Adam Heyward at (703) 308-6422.

Sincerely,

Betty Shackleford for

Frank Sanders, Director
Antimicrobials Division (7510C)

REREGISTRATION ELIGIBILITY

DECISION

for

Pine Oil

Case Number 3113

Approved by:

Frank T. Sanders, Director
Antimicrobials Division

10/2/06

Date

Attachment

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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDI	Estimated Daily Intake
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern

LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
Ppb	Parts per Billion
PCCs	Poison Control Centers
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Pine Oil Reregistration Team

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ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for Pine Oil and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of Pine Oil that pose risks of concern. As a result of this review, EPA has determined that Pine Oil-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The 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 (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. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be accomplished through this reregistration process. The Act also required that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for pine oil.

The Agency has concluded that the FQPA Safety Factor for pine oil should be removed (equivalent to 1X) based on: (1) the use of conservative NOAEL values from the developmental toxicity study for calculation of dietary and non-dietary endpoints and; (2) there is no evidence of increased susceptibility from exposure to pine oil from the data available.

Risks summarized in this document are those that result only from the use of the active ingredient pine oil. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for pine oil and any other substances. Pine oil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that pine oil has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on

EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of pine oil. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting document for pine oil referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0302).

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of pine oil, and its regulatory history. Section III, Summary of Pine Oil Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

The first pine oil registration was issued in December, 1947. Currently there are 88 active pine oil registrations (19 technical products and 69 end-use products) registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

B. Chemical Identification

Chemical Identification	
Chemical Name	1-Methyl-4-isopropyl-1-cyclo-hexen-8-ol
Common/Trade Names	Pine Oil 80
Chemical Family	alpha-Terpineol and Terpinolene (Terpene alcohol)
CAS Number	8002-09-3
Case Number	3113
OPP Chemical Code	067002
Molecular Formula	$C_{10}H_{18}O$
Molecular Structure	CH_3-C_6H_9-(OH)-C_3H_5

Physical/Chemical Properties	
Parameter	Value
Molecular Weight	154.0
Color	Colorless to pale yellow
Physical State	Liquid
Specific gravity	0.952 at 20 ^oC
Boiling Point	~ 210 ^{o} C at 750 mm Hg
Dissociation Constant	NA (insoluble in water)
pH	NA (insoluble in water)
Stability	30-day accelerated storage study showed the substance is stable
Melting point	N/A

Physical/Chemical Properties	
Parameter	Value
Water Solubility	Insoluble in water (immiscible)
Solubility in organic solvents	Isopropyl alcohol >90% Toluene >90%
Octanol-water Partition Coefficient	Can not be determined (insoluble in water)
Vapor Pressure	0.2 mm Hg at 20°C

C. Use Profile

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

Types of Pesticide: Disinfectant, sanitizer, mircobicide/microbistat, virucide, insecticide

Use Sites:

Indoor Non-Food

Eating Establishments (Non-Food Contact)
Commercial, Institutional and Industrial Areas/Premises
Commercial, Institutional or Industrial Equipment
Commercial Transportation Facilities (Non-Food Contact)
Laundry Equipment
Refuse and Solid Waste Transportation and Handling Equipment
Hard Non-Porous Surface Treatments
Automobiles and Ships

Indoor Residential

Household or Domestic Dwellings
Household or Domestic Dwelling Contents
Bathroom Premises
Human Bedding
Human Grooming Instruments
Laundry (Household/Coin-Operated)
Refuse and Solid Waste Containers (Garbage Cans)
Refuse and Solid Waste Sites
Refuse and Solid Waste Transportation and Handling Equipment
Hard Non-Porous Surface Treatments

Toilet Bowls and Urinals
Pets (All or Unspecified)

Indoor Medical

Barber and Beauty Shop Equipment
Barber and Beauty Shop Instruments
Cuspidors and Spittoons
Laundry (Hospital)
Household Sickrooms
Hospitals and Related Institutions
Hospital Non-Critical Items (Items contact only unbroken skin)

Target Pests:

Brevibacterium ammoniagenes, candida albicans, enterobacteraerogenes, escherichia coli, gram-negative enteric bacteria, household germs, gram-negative household germs such as those causing salmonellosis, herpes simplex types 1 and 2, influenza type A, influenza virus type A/Brazil, influenza virus type A2/Japan, intestinal bacteria, klebsiella pneumoniae, odor-causing bacteria, mold, mildew, pseudomonas aeruginosa, salmonella choleraesuis, salmonella typhi, salmonella typhosa, serratia marcescens, shigella sonnei, staphylococcus aureus, streptococcus faecalis, streptococcus pyogenes, trichophyton mentagrophytes.

Formulation Types: Soluble concentrates, ready-to-use liquid solutions, and pressurized sprays

Method and Rates of Application:

Equipment: Applied to surfaces by wiping, mopping, mechanical scrubber or immersion

Application Rates:

Indoor Food: If concentrate, add 4 Tbsp. to 1/4 cup of pine oil to one gallon water. Wet surface thoroughly for 10 minutes. Rinse with clear water. If ready-to-use, apply pine oil, let stand for 10 minutes then rinse with clear water.

Indoor Non-Food:

Eating Establishments: If concentrate, add 4 Tbsp. to 1/4 cup pine oil to one gallon water. Apply with mop or sponge. Let stand 10 minutes and wipe off excess. For heavily soiled areas, up to ½ gallon pine oil to ½ gallon water may be used.

Commercial, Institutional, and Industrial areas or equipment: If concentrate, add 4 Tbsp. to 1/4 cup pine oil to one gallon water. Apply with mop or sponge. Let stand 10 minutes and wipe off excess. For heavily soiled areas, up to ½ gallon pine oil to ½ gallon water may be used.

Laundry: Use full strength on soiled areas and add ½ cup to wash.

Indoor Residential:

Household and Domestic Dwellings and Contents: If concentrate, add 4 Tbsp. to 1/4 cup of pine oil to one gallon water. Wet surface thoroughly for 10 minutes. Rinse with clear water. If ready-to-use, apply pine oil, let stand for 10 minutes then rinse with clear water.

Pet Baths: Use 3 Tsp to 3 Tbsp. per gallon of water.
Garbage Pails: Use 2 Tbsp. per gallon of water.
Diapers: Soak in 6 Tbsp. per 3 gallons water.

Indoor Medical:

Hospitals and Related Institutions: If concentrate, add 4 Tbsp. to 1/4 cup of pine oil to one gallon water. Wet surface thoroughly for 10 minutes. Rinse with clear water. If ready-to-use, apply pine oil, let stand for 10 minutes then rinse with clear water.

Barber and Beauty Shop Equipment and Instruments: If concentrate, add 4 Tbsp. to 1/4 cup of pine oil to one gallon water. Wet surface thoroughly for 10 minutes. Rinse with clear water. If ready-to-use, apply pine oil, let stand for 10 minutes then rinse with clear water.

Laundry: Use full strength on soiled areas and add ½ cup to wash.

Use Classification: General

III. Summary of Pine Oil Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for pine oil. While the risk assessments and related addenda are not included in this document, they are available to the public in EPA's Pesticide Docket EPA-HQ-OPP - 2004-0302 at http://www.regulations.gov . Hard copies of these documents may be found in the OPP public docket. The OPP public docket is located in Room S-4900, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

The Agency's use of human studies in the pine oil risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

1. Toxicity of Pine Oil

A brief overview of the toxicity studies used for determining endpoints in the dietary risk assessments are outlined below in Table 2. Further details on the toxicity of pine oil can be found in the *Pine Oil Risk Assessment for the Reregistration Eligibility Decision*, dated May 23, 2005. This document is available on Agency's website in the EPA Docket at http://www.regulations.gov.

The Agency has reviewed all toxicity studies submitted for pine oil and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. Major features of the toxicology profile are presented below. In acute toxicity studies, pine oil was shown to be of low toxicity, with the exception of an eye irritation study, which was Toxicity Category II. Pine oil is also a moderate skin irritant.

Table 1. Acute Toxicity of Pine Oil

Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100 Acute oral toxicity-Rat	40253502	LD_{50}(combined) = 2.7 g/kg	III
870.1200 Acute Dermal toxicity-Rat	40253503	LD_{50} > 2000 mg/kg	III
870.1300 Acute inhalation toxicity-Rat	43375208	LC_{50} > 3.67 mg/L	IV

Table 1. Acute Toxicity of Pine Oil			
Guideline No./ Study Type	**MRID No.**	**Results**	**Toxicity Category**
870.2500 Dermal irritation-Rabbit	43375210	Erythema/edema up to 7 days post dose	III
870.2400 Primary Eye Irritation	43375209	Irritation lasting up to 16 days	II
870.2600 Skin sensitization-Guinea pig		Not a sensitizer. Study unacceptable	

The doses and toxicological endpoints selected for the dietary risk assessment are summarized in Table 2 below.

Table 2. Toxicological Endpoints			
Exposure Scenario	**Dose used in risk assessment UF /MOE**	**FQPA SF and Endpoint for Risk Assessment**	**Study and Toxicological Effects**
Dietary Risk Assessments			
Acute Dietary (gen pop)	NOAEL of 50 mg/kg/day UF= 100x DB UF =10x **Acute RfD** = 0.05 mg/kg/day	FQPA SF = 1x **aPAD=**acute RfD / FQPA = 0.05 mg/kg/day	Developmental toxicity study in rats Maternal LOAEL of 600 mg/kg/day based on clinical observations of toxicity, decreased body weight, weight gain, food consumption
Acute Dietary (females 13+)	NOAEL of 50 mg/kg/day UF= 100x DB UF = 10x **Acute RfD** = 0.05 mg/kg/day	FQPA SF = 1x **aPAD=**acute RfD / FQPA = 0.05 mg/kg/day	Developmental toxicity study in rats Developmental toxicity LOAEL of 600 mg/kg/day based on decreased fetal weight, fetal malformations, and retardation of ossification.
Chronic Dietary	NOAEL= 50 UF= 300 DB UF = 10x **Chronic RfD** = 0.05 mg/kg/day	FQPA SF = 1x **cPAD=**chronicRfD / FQPA = 0.016 mg/kg/day	Developmental toxicity study in rats Maternal LOAEL of 600 mg/kg/day based on clinical observations of toxicity, decreased body weight, weight gain, food consumption

Notes:
UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, RfD = reference dose, MOE = margin of exposure, DB UF= Database Uncertainty Factor

General Toxicity Observations

A short-term dermal endpoint was not established for pine oil. This conclusion was based on the results of a 14-day dermal toxicity study (submitted with the 90-day dermal toxicity study) in which no adverse dermal effects were observed at a dose near a limit dose (940 mg/kg/day).

Uncertainty Factors

In addition to the standard inter-and intra-species 10x uncertainty factors, additional factors were applied based on the lack of specific neurotoxicity and reproductive toxicity endpoints and uncertainty in characterization of pre- and post-natal toxicity. Specific uncertainty factors were applied to the doses established for each exposure route as follows:

10x = interspecies extrapolation
10x = intraspecies variation
10x = database UF for lack of an adequate hazard database
3x = lack of a chronic toxicity study (applied to the shorter-term toxicity studies to extrapolate to chronic dietary and long-term inhalation)

Dietary

The acute RfD is 0.05 mg/kg/day, established in a developmental toxicity study in rats. The acute RfD was determined based on a maternal Lowest Observed Adverse Effect Level (LOAEL) of 600 mg/kg/day based on clinical observations of toxicity, decreased body weight, weight gain, food consumption for the general population. The Non-observable Adverse Effect Level (NOAEL) was 50 mg/kg/day.

The chronic RfD is 0.05 mg/kg/day, established in a developmental toxicity study in rats. The acute RfD was determined based on a maternal (LOAEL) of 600 mg/kg/day based on clinical observations of toxicity, decreased body weight, weight gain, food consumption. The NOAEL was 50 mg/kg/day.

Incidental Oral

The short-term, and intermediate-term incidental oral endpoint of 50 mg/kg/day is based on clinical observations of toxicity, decreased body weight, weight gain, and food consumption at 600 mg/kg/day in maternal animals in the rat developmental study. Thus, the target margin of exposure (MOE) is 100 for short-term exposures and 1,000 for intermediate-term exposures.

Short-, Intermediate- and Long-term Dermal

An endpoint for short-term dermal risk assessment was not identified based on the results of a 14-day dermal toxicity study (MRID 405154010) in which no adverse dermal effects were observed at a dose near a limit dose (940 mg/kg/day).

For intermediate and long-term dermal, a NOAEL of $\geq$ 226 mg/kg/day was established based on a 90-day dermal toxicity study in rats. The target MOE is 100. Extra uncertainty factors were not applied to the dermal endpoint based on the

conservative nature of the dose level (i.e. 226 mg/kg/day vs. 940 mg/kg/day in the 14 day dermal study) and the observation that higher dose levels could not be tested dermally.

Inhalation (all durations)

The inhalation endpoint for all exposure durations is 50 mg/kg/day and is based on clinical observations of toxicity, decreased body weight, weight gain, and food consumption at 600 mg/kg/day in maternal animals in the rat developmental study. Uncertainty factors were included for inter-species extrapolation (10x), intra-species variation (10x), and lack of an adequate hazard database including a route-specific inhalation study (10x) for the short-term inhalation endpoint. For the intermediate and long-term endpoint, an additional uncertainty of 3x was applied for the lack of a long-term study from which to determine a long-term exposure endpoint. Thus, the MOE is 1,000 for short- and intermediate-term exposures and 3,000 for long-term exposures.

Carcinogenicity

Pine oil has not been classified as to carcingenicity; however, these data are not required at this time.

.

Mutagenicity

Acceptable mutagenicity studies including Ames Salmonella assay and micronucleus assay were conducted with pine oil. No mutagenic response was observed in these studies. However, in an unacceptable *in vitro* cytogenetics assay a negative mutagenic response was observed. This study was deemed unacceptable due to problems with the integrity of the cell cultures and must be repeated to confirm the negative result from the unacceptable study.

Neurotoxicity

Neurotoxicity studies conducted with pine oil were not available.

Endocrine Disruption Potential

EPA is required under the Federal Food Drug and Cosmetic Act (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 such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be

added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupting Screening Program (EDSP) have been developed, Pine Oil may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for pine oil based on: (1) the use of conservative NOAEL values from the developmental toxicity study for calculation of dietary and non-dietary endpoints and; (2)there is no evidence of increased susceptibility to infants and children from exposure to pine oil, based on available data. Based on the analysis of submitted developmental toxicity studies, the Agency determined that no special FQPA Safety Factor is needed since there were no residual uncertainties for pre- and/or postnatal toxicity.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. The Agency has conducted a dietary exposure and risk assessment for the use of Pine Oil on food-contact surfaces.

a. Acute PAD

Acute dietary risk for pine oil is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. The aPAD is the acute reference dose (0.05 mg/kg/day) modified by the FQPA safety factor. The acute reference dose was derived from a developmental toxicity study in rats in which both the NOAEL (50 mg/kg/day) and the LOAEL (600 mg/kg/day) were determined. Acute dietary exposure was estimated for females ages 13-49 and for the general population. The pine oil aPAD is 0.05 mg/kg/day based on a reference dose of 0.05 mg/kg/day, and incorporating the FQPA safety factor of 1X.

b. Chronic PAD

Chronic dietary risk for pine oil is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose (0.05 mg/kg/day) modified by the FQPA safety factor. The cPAD was derived from developmental toxicity study in rats in which both the NOAEL (50 mg/kg/day) and the LOAEL (600 mg/kg/day) were

determined based on clinical observations of toxicity, decreased body weight, weight gain, food consumption. The pine oil cPAD is 0.016 mg/kg/day based on a reference dose of 0.05 mg/kg/day, which includes the incorporation of the FQPA safety factor (1X) for the overall U.S. population or any population subgroups. Uncertainty factors were also included for inter-species extrapolation (10x), intra-species variation (10x), lack of an adequate hazard database (10x), and lack of a long-term study (3x).

4. Dietary Exposure Assumptions

Acute and chronic dietary exposure assessments were assessed for the indirect food-contact surface use. This assessment was conducted using FDA assumptions for residues, migration, and surface area of exposure from application to food-contact surfaces. The assessment for the disinfectant was conducted by relying upon models developed by the FDA to estimate dietary exposure, through the indirect food contact use of pine oil. In estimating the dietary exposure from the disinfectant use of pine oil, the Agency has made the following assumptions:

1. Residual solution of the formulation on Surface: 1 mg/cm^2 (FDA's worst case scenario)

2. Area of treated surface: 2000 cm^2 (50% of the FDA worst case assumption)

3. EPA assumed that in all scenarios listed on product labels, the maximum exposure of food (indirect contact) is 2000 cm^2, including use on drain boards.

4. Based on directions on product labels, the Agency assumed that there will be a potable water rinse following application of the disinfectant. Although there are quantitative approaches to measuring the reduction in residue, the Agency has assumed a 90% reduction in residue level as reasonable. Hence the dietary exposure risk assessment is carried out based on the 90% reduction scenario**.**

For more details on the exposure estimates and dietary risk, see *Pine Oil Risk Assessment November 1, 2005*, available under docket number EPA-HQ-OPP-2004-0302 on www.regulations.gov.

5. Dietary Risk Assessment

a. Dietary Risk from Food

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. A summary of acute and chronic risk estimates are shown in Table 3.

Screening-level dietary risk assessments were conducted for the indirect food uses of pine oil. Dietary risk estimates are provided for males, females and children. The results using

the FDA model show that there is only one dietary exposure scenario that presents an unacceptable dietary risk.

Table 3. Dietary Exposure and Risk			
Formulation	**Exposure (mg/kg/day) (males)**	**% aPAD**	**%cPAD**
7.9% Pine Oil	0.0035	7.0	7.0
3.95 % Pine Oil	0.0035	7.0	7.0
23.81% Pine Oil	0.0034	7.0	7.0
60% Pine Oil	0.0267	53	53
19.9% of Pine Oil	0.0084	17	17
Formulation	**Exposure (mg/kg/day) (females 13- 50 years old)**	**% aPAD**	**%cPAD**
7.9% Pine Oil	0.0041	8.0	8.0
3.95 % Pine Oil	0.0041	8.0	8.0
23.81% Pine Oil	0.0039	8.0	8.0
60% Pine Oil	0.0311	62	62
19.9% of Pine Oil	0.0098	20	20
Formulation	**Exposure (mg/kg/day) (children 1-6 years old)**	**% aPAD**	**%cPAD**
7.9% Pine Oil	0.0164	32	32
3.95 % Pine Oil	0.0164	32	32
23.81% Pine Oil	0.0158	32	32
60% Pine Oil	0.124	248	248

19.9% of Pine Oil	0.039	78	78

PAD=Population Adjusted Dose (acute or chronic)
%PAD = EDI/aPAD or cPAD * 100, where aPAD=0.05 mg/kg/day and cPAD=0.0161 mg/kg/day

b. Dietary Risk from Drinking Water

The dietary risk assessment conducted for the antimicrobial use of Pine Oil considered only potential food exposures from the antimicrobial uses of Pine Oil because these uses are not likely to contaminate surface or ground water and are expected to have minimal impact on drinking water exposure.

6. Residential Exposure Assessment

Residential exposure from pine oil can occur from the antimicrobial uses of Pine Oil. The residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food and drinking water. Exposure may occur during and after application methods including application to hard surfaces as a cleaner, disinfectant, sanitizer, fungicide, mildewstat, and deodorizer. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose. Based on the application methods, pine oil has been assessed for the residential mixing/loading/applicator (or "handler") exposure.

a. Residential Toxicity

The toxicity endpoints and associated uncertainty factors used for assessing the non-dietary risks for pine oil are listed in Table 4.

A MOE greater than or equal to 3,000 is considered adequately protective for the residential exposure assessment for the inhalation route of exposure. The MOE of 3,000 includes 10x for interspecies extrapolation, 10x for intraspecies variation, 3x for a lack of chronic toxicity data and the 10x Uncertainty factor. For the incidental oral route of exposure, a MOE greater than or equal to 1,000 is considered adequately protective for the residential exposure assessment. The MOE of 1,000 includes 10x for interspecies extrapolation, 10x for intraspecies variation and the 10x Uncertainty factor.

Table 4. Non-Dietary Risk Assessments

Incidental Oral Short– and Intermediate-Term (1 - 30 Days, and 1-6 months)	Maternal NOAEL= 50 mg/kg/day	**Target MOE**= 100 (short-term) 1000 (intermediate-term)	Developmental toxicity study in rats Maternal LOAEL of 600 mg/kg/day based on clinical observations of toxicity, decreased body weight, weight gain, food

			consumption
Dermal Short -term	Endpoint Not Identified		
Dermal intermediate and long-term	Dermal NOAEL ≥ 226 mg/kg/day	**Target MOE**=100 (residential and occupational)	90-day dermal toxicity study in rats Dermal NOAEL of ≥ 226 mg/kg/day (highest dose tested)
Inhalation All durations	NOAEL = 50 mg/kg/day (assume inhalation and oral absorption are equivalent, i.e., 100%)	**Target MOE** =1,000 (ST, IT) = 3,000 (LT) (residential and occupational)	Developmental toxicity in rats Maternal LOAEL of 600 mg/kg/day based on clinical observations of toxicity, decreased body weight, weight gain, food consumption.

b. Residential Handler Exposure

The residential handler scenarios considered in this assessment include handling of liquid general purpose cleaner and dog washing. These scenarios were selected because they are believed to yield the greatest amount of handler exposure to pine oil.

i. Exposure Assessment

The following two scenarios were considered for residential handlers of pine oil-containing cleaning products:

- Use of cleaner/disinfectant/deodorizing wipe on hard non-porous surfaces, and
- Use of cleaner/disinfectant/deodorizing mopping on hard non-porous surfaces.

ii. Residential Risk

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments. The inhalation risk assessment for the wiping and mopping scenarios are presented below in Table 5. Using the CMA (Chemical Manufacturers Association) data, the calculated inhalation MOEs (all durations) for the wiping and mopping are not of concern because the estimated MOEs of 5,300 and 20,000, respectively, are above the target MOE for 1,000. This estimate is based on a product with 80 percent active ingredient. The risks associated with use of a product with a lower percent of pine oil will be proportionately less.

Residential exposure to pine oil products used for washing dogs (i.e., specified on label as a “dog bath”) is believed to be best represented by the short-term exposure duration.

Therefore, because a short-term dermal endpoint was not identified (i.e., determined not to be of concern) no estimates are presented for the dermal exposure to homeowners bathing a dog. However, because pine oil has a relatively high vapor pressure, the model EFAST was used to assess the potential short-term inhalation exposure. However, EFAST does not contain an exposure scenario for bathing a dog. Therefore, to determine the potential inhalation exposure to pine oil when used to bathe a dog, the air concentration estimate for general purpose cleaners was used as a screening-level assessment. The results of the EFAST model exposure of 0.035 mg/kg/day indicate an inhalation MOE (all exposure durations) from the vapor of pine oil to be 1,400. Therefore, the vapor inhalation portion of pine oil is not of concern (i.e., above the target MOE of 1,000). Further details on the residential assessment can be found in the *Residential and Occupation Risk Assessment for Pine Oil*, dated November 1, 2005, available in EPA's public docket at www.regulations.gov.

Table 5. Calculation of Dermal and Inhalation MOEs based on CMA Data for Residential Handlers

Exposure Scenario	Method of Application	Dermal Unit Exposure (mg/lb ai) [b]	Inhalation Unit Exposure (mg/lb ai) [c]	Appl. Rate [d] (lb a.i./ gal)	Amount Treated	Absorbed Dermal Dose (mg/kg/day) [f]	Dermal MOE [g]	Inhalation Dose (aerosol) (mg/kg/day) [h]	Inhalation (aerosol) MOE [i]
Hard Surface Disinfection	Wiping	2870 (CMA no glove)	67.3 (CMA)	0.075	0.5 liter of product (0.13 gal)	0.40	570	0.0094	5,300
	Mopping	71.6	2.38	0.075	1 gallon	0.077	2,900	0.0026	20,000

b Dermal unit exposures are from CMA (USEPA 1999; long pants, long-sleeved shirt, no gloves).

c Inhalation unit exposures are from CMA (USEPA 1999).

d Application rates are based on the pine oil labels (1.5 oz/gal x 1 gal/128 oz x 8 lb/gal x 80% ai)

f Dermal dose (mg/kg/day) = [unit exposure (mg/lb ai) * Appl. rate (lb ai/gallon) * gallons handled / Body weight (70 kg).

g Intermediate-term Dermal MOE = NOAEL (mg/kg/day) / Daily Dose [Where intermediate-term dermal NOAEL = 226 mg/kg/day]. Target MOE is 100. Note: Short-term not of concern.

h Inhalation dose (mg/kg/day) = [unit exposure (mg/lb ai) * max appl rate (lb ai/gal) * gallons handled * 100% inhalation absorption] / Body weight (70 kg).

i Inhalation MOE = LOAEL (mg/kg/day) / Daily Dose [LOAEL for all durations = 50 mg/kg/day]. Target MOE is 1000 for short- and intermediate-term.

c. Residential Post-application

i. Exposure Assessment

Post-application exposures can occur to toddlers from the dermal, oral (incidental) and inhalation routes from floors that have been mopped with a product containing pine oil and from wearing or mouthing treated clothing/diapers. Additionally, adults may be exposed to inhalation exposures after use. Residential floors are assumed to be washed/moped on an intermittent basis (e.g., weekly), facilities such as day care centers may clean the floors more often. Therefore, the intermediate-term dermal risks have been presented (no short-term dermal endpoints of concern). In addition, both the short- and intermediate-term incidental oral endpoints are provided to assess the potential risks. The short- and intermediate-term post-application inhalation exposure to pine oil vapors are also of potential concern.

ii. Risk Assessment

Dermal

There is the potential for intermediate-term dermal exposure to toddlers wearing treated clothing/diapers and crawling on the floors where cleaning occurs more often than in a residence, such as at day care facilities. There is also the potential exposure to toddlers playing

and/or sleeping with treated dogs. The duration of exposure is expected to be short-term because of the intermittent bathing of dogs and the relatively high vapor pressure of pine oil. Although there is no dermal endpoint of concern for the short-term duration, inhalation exposure and risks are presented. The calculation of the dermal dose and the dermal MOE are presented below in Table 6. The dermal MOE is estimated to be 570 which is above the target MOE of 100, and therefore not of concern.

Table 6. Intermediate-term Risks Associated with Post application Dermal Exposure on Treated Floors.

Parameter	Value	Rationale
Application Rate	1000 ft^2/gallon of solution	USEPA Assumption
Cleaning Solution	0.075 lb ai/gallon	Maximum rate listed on label (EPA Reg. No. 4313-9)
Transferable Residues (TR)	9.2 mg/m^2/day	((0.075 lb ai/gal)/(1000ft^2 per gallon)) * (25% remaining)* (10% transfer) * (Conversion Factors)
Surface Area of Body in Contact with Carpet	0.657 m^2	Median surface area of toddler
Body Weight	15 kg	Median body weight of toddler
Potential Dermal Exposure	0.40 mg/kg/day	TR * SA/ BW
Dermal NOAEL	226 mg/kg/day	
Dermal MOE	570	(Dermal NOAEL) / (Daily Dermal Dose). Target MOE = 100.

TR = [((0.075 lb ai/gal /1000ft^2) x (454 g/lb) x (1000 mg/g) x (1 ft^2 / 0.093 m^2)) x (0.25 remaining) x (0.1 transferable)]

Incidental Ingestion

In addition to dermal exposure, infants crawling on treated floors and mouthing treated clothing may also be exposed to pine oils via incidental oral exposure. To calculate incidental ingestion exposure to pine oils due to hand-to-mouth transfer from the mopping and wiping of floors, the scenarios established in the *Standard Operating Procedures (SOPs) for Residential Exposure Assessments* were used. The assumptions in the above table estimate the transferable residues as 0.92 µg/cm^2 (equivalent to 9.2 mg/m^2). The surface area used for each hand-to-mouth event is 20 cm^2. It is assumed that there are 20 hand-to-mouth exposure events per hour (90^{th} percentile) for the short-term duration and 9.5 events per hour for the intermediate-term duration (mean). The short-term incidental oral NOAEL of 50 mg/kg/day (target MOE = 100) is believed to best represent the homeowner uses because of the intermittent nature of cleaning the floor and the intermediate-term duration best represents uses in day care centers. The intermediate-term incidental oral NOAEL is the same but the target MOE is 1,000.

The potential dose rate (PDR) using this equation for the short-term exposure is 0.052 mg/kg/day and 0.023 mg/kg/day for the intermediate-term, resulting in a hand-to-mouth short-term MOE for toddlers of 960 and 2,200 for the intermediate-term. Therefore, the incidental oral exposure is not of concern for either exposure duration (i.e., above the target MOE).

For the incidental oral exposure to toddlers from mouthing treated clothing, post-application exposure to the laundry detergent additive use was selected to represent all post-application laundry cleaning scenarios (i.e., pre-soak, spot, laundry detergent additive). To determine post-application dermal (intermediate-term) and incidental oral (short- and intermediate-term) exposure to treated clothing via the laundry additive use, the guidance provided in Human and Environmental Risk Assessment (HERA) Guidance Document (2003) was used for *indirect skin contact from wearing clothes* and *oral exposure from mouthing or sucking on treated fabric*. The short- and intermediate-term incidental oral MOEs that result from estimating risks from mouthing treated fabric is well over the short-term target of 100 and the intermediate-term target of 1000 and are not of concern. For additional information, please see the Addendum to Residential Occupational and Residential Exposure Assessment of Pine Oil for the Reregistration Eligibility Decision Document (RED), dated June 20, 2006.

Inhalation

Post application inhalation exposure to adults and toddlers may occur after pine oil has been used as a general cleaner and/or dog bath. No post application air concentration data have been submitted to determine potential inhalation risk. Therefore, the EFAST model was used to present a screening-level estimate of the potential inhalation risk. The inhalation toxicological endpoint represents both the short- and intermediate-term exposure durations. The post application estimates are based on the EFAST results for the air concentration and inhalation dose from the adult handlers. The toddler risk estimates are corrected for the lower body weight (i.e., 15 kg) and breathing rate (i.e., 8.3 m^3/day).

The daily dose rate is based on the EFAST average daily concentration of 0.19 mg/m^3. The inhalation MOE for adults is not of concern (i.e., MOE = NOAEL of 50 mg/kg/day / 0.035 mg/kg/day = 1,400, target MOE of 1,000). However, based on the same scenario, the toddler short-term inhalation risk is of concern because of the difference in body weight and breathing rate (i.e., MOE = NOAEL of 50 mg/kg/day / 0.11 mg/kg/day = 450, target MOE of 1,000).

EFAST was also used to estimate the potential inhalation risks resulting from the treatment of dogs. Although EFAST does not provide a scenario for pets, it does provide a screening-level assessment for cleaning products. Based on the cleaning product scenario and a weight fraction of 0.00078 (pine oil dog wash solution concentration), the acute adult dose rate is 0.0068 mg/kg/day. The short-term inhalation MOE is 7,400 and is not of concern (short-term target MOE is 1,000).

7. Aggregate Risk

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

a. Short-and Intermediate-Term Aggregate Risk

Aggregate dietary risk includes exposure from food and drinking water. Pine oil is not expected to impact drinking water from the currently registered uses as noted above. In Table 3 of this document, the risks estimates for use of the 60 percent pine oil formulation show a dietary risk of concern for acute and chronic exposure in children.

Short-, intermediate-, and long-term risks typically involves exposure from dietary sources (food and water) in combination with residential scenarios that have a reasonable chance of co-occurrence. In the case of pine oil, residential exposures are not expected to be long-term, only short-or intermediate-term in duration. Thus, there is no long-term aggregate risk assessment.

For the short-term aggregate assessment for adult exposures, the dietary and inhalation exposures from cleaning were aggregated. The study and endpoint describing the effects from these two routes of exposure were the same. The dermal exposure is not included.

For toddlers, dietary exposure is aggregated with the incidental oral exposure from the floor cleaning. The aggregate risks associated with mouthing treated clothing were not included in the aggregate assessment as the MOEs for these scenarios are so above the target MOE that it is estimated that including this use in the aggregate assessment will have no impact. There are no aggregate intermediate-term scenarios for toddlers, although there are intermediate-term exposure scenarios.

Aggregate MOE calculations were performed using the Aggregate Risk Index method (EPA, 2001). As shown in Table 7, no aggregate risks of concern were identified for either males or females, as the ARI value is above 1 for both. However, as shown in Table 8, the ARI for children/toddlers ranges from 0.17-0.4, which is below the target ARI of ≥1, and thus, exceed the Agency's level of concern. Further details on the aggregate risk assessment of pine oil can be found in the *Pine Oil Risk Assessment for the Reregistration Eligibility Decision*, dated January 5, 2005.

Table 7: Aggregate Short-term Risks for Adult Males					
Formulation	Dietary exposure	Dietary MOE[1]	Inhalation exposure[2] (mg/kg/day)	Inhalation MOE	total MOE
7.9% Pine Oil	0.0035	14285	0.0094	5300	4000
3.95 % Pine Oil	0.0035	14285			4000
23.81% Pine Oil	0.0034	14705			4032
60% Pine Oil	0.0267	1872			1408
19.9% of Pine Oil	0.0084	5952			2941
Aggregate Short-term Risks for Adult Females					
Formulation	Dietary exposure (mg/kg/day)	Dietary MOE[1]	Inhalation exposure[2] (mg/kg/day)	Inhalation MOE	total MOE
7.9% Pine Oil	0.0041	12200	0.0094	5300	3800
3.95 % Pine Oil	0.0041	12200			3800
23.81% Pine Oil	0.0039	12800			3900
60% Pine Oil	0.0311	1600			160
19.9% of Pine Oil	0.0098	5100			2700

[1]Dietary MOE = short-term incidental oral NOAEL / food exposure
[2]inhalation exposure from a cleaning product (wiping)
Target MOE is 1000.

Table 8. Aggregate Short-term Risks for Children/Toddlers						
Formulation	Dietary Exposure	Dietary MOE[1]	Diet MOE/UF[2]	Inhalation exposure[3] (mg/kg/day) (MOE) MOE/UF	Incidental Oral exposure[4] (mg/kg/day) (MOE) MOE/UF	ARI
7.9% Pine Oil	0.0164	3048	3.0	0.11 (MOE =450) 0.45	0.052 (MOE=960) 0.96	0.4
3.95 % Pine Oil	0.0164	3048	3.0			0.4
23.81% Pine Oil	0.0158	3164	3.1			0.4
60% Pine Oil	0.124	403	0.4			0.17
19.9% of Pine Oil	0.039	1282	1.2			0.25

[1]Dietary MOE = short-term incidental oral NOAEL / food exposure
[2]MOE/UF = calculated MOE / chronic dietary UF [1000]
[3]inhalation post-application exposure from cleaning product
[4]Incidental oral exposure from treated floors

b. Dermal Aggregate Risk

Dermal exposures are considered short-term only except for the toddler dermal scenarios from crawling on treated floors and wearing treated clothing. For pine oil, no short-term dermal endpoint was identified in the available toxicology database. As there are only two quantified dermal scenarios, and these risks are well beyond the target MOE, no aggregation of dermal exposure is performed for pine oil.

8. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of pine oil use pine oil-containing products in commercial/institutional settings (including industrial and medical uses). Occupational risk for all of these potentially exposed populations is measured by a MOE which determines how close the occupational exposure comes to a No Observed Adverse Effect Level

(NOAEL) from toxicological studies. In the case of pine oil, MOEs greater than 100 are not of concern to the Agency. This MOE includes the standard safety factors of 10X for intraspecies variability (i.e. differences among humans) and 10X for interspecies variability (differences between humans and animals). For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely re-enter.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure). Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose. Occupational risks were assessed for exposures from powder formulations, as all products are in this form.

For more information on the assumptions and calculations of potential risk of pine oil to workers, see the Occupational Exposure Assessment (Section 6) in the *Pine Oil Risk Assessment for the Reregistration Eligibility Decision,* dated January 5, 2005.

a. Occupational Toxicity

The toxicological endpoints used in the occupational assessment can be found in Table 2 above.

b. Occupational Handler Exposure

Occupational handler risk estimates have been assessed for pine oil using surrogate unit exposure data from the Chemical Manufacturers Association (CMA) database, application rates from labels, and EPA estimates of daily amount handled. Specifically, it was assumed that occupational handlers will use 1.5 ounces of liquid pine oil-containing 80% product diluted in 1 gallon of water for low pressure spray, wiping, and mopping application methods. Therefore, the use amount for the application of diluted cleaning solutions is 0.075 lb ai/gallon for the low pressure spray, wiping, and mopping application methods. For spraying and mopping it is assumed that 2 gallons (each) are used for daily cleaning and that 1 liter is used for wiping.

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle pine oil during the usual use patterns associated with the pesticide's use. Based on the use patterns, the handling of pine oil-containing cleaning products through low pressure spray, wiping, and mopping application methods was assessed.

c. Occupational Handler Risk Summary

There are no chemical-specific exposure data to assess cleaning product applications. Therefore, dermal and inhalation exposures were assessed for low pressure spray, wiping, and mopping application methods using surrogate data. Specifically, values from the Chemical Manufacturers Association (CMA) antimicrobial study (U.S. EPA, 1999) were used. The dermal and inhalation exposures from these techniques have been normalized by the amount of active ingredient handled and reported as unit exposures (UE) expressed as mg/lb ai handled. In addition, product label maximum application rates, related use information, and Agency standard

values were used to assess occupational handler exposures. .

The results of the risk assessment are presented in Table 9. The calculated MOEs indicate that aerosol-generated inhalation exposure risks are not of concern (i.e., MOEs ≥ 1,000) for short- and intermediate- term exposures under all scenarios assessed. For dermal exposure, the calculated MOEs indicate that risks do not exceed the Agency's level of concern for the low pressure spray, wiping and mopping scenarios (i.e., MOE > 100).

The aerosol-generated inhalation exposure and risk estimates from the CMA data discussed above do not account for the potential vapor inhalation exposure to pine oil (pine oil has a relatively high vapor pressure). Therefore, the potential vapor inhalation exposure to handlers is addressed by modeling of the air concentrations. Based on these assumptions, the short- and intermediate-term vapor-derived inhalation risks are not of concern (i.e., MOE of 1,400 greater than the target MOE of 1000 for the average daily dose).

Table 9. Estimates of Exposure and Risks to Primary Occupational Handlers of Pine Oil

Exposure Scenario	Dermal Dose (mg/kg/day)[a]	Inhalation Dose (mg/kg/day)[b]	Dermal MOE [c]	Inhalation MOE [d]
Cleaning products - Low pressure sprayer	0.41	0.0015	550	34,000
Cleaning products - Wiping	0.81	0.019	280	2,600
Cleaning products - Mopping	0.15	0.0051	1,500	9,800

[a] Abs. Dermal Dose (mg/kg/day) = [Appl. rate (lb ai/gallon) * Gallons handled * Unit Exposure (mg/lb ai)] / Body Weight (70 kg)]. Clothing attire is long pants, long sleeved shirts, and no gloves.

[b] Inhalation Dose (mg/kg/day) = [Appl. rate (lb ai/gallon) * Gallons handled * Unit Exposure (mg/lb ai) * 100% Inhalation Absorption] / Body Weight (70 kg).

[c] Dermal MOE= Dermal NOAEL (226 mg/kg/day)/Dermal Dose (mg/kg/day). Target MOE is 100.

[d] Inhalation MOE= Inhalation NOAEL (50 mg/kg/day)/ Inhalation Dose (mg/kg/day). Target MOE is 1,000 for short- and intermediate-term exposure.

d. Occupational Post-application Risk Summary

Occupational post application dermal and aerosol-generated inhalation exposures to pine oil are likely to be minimal compared to handler exposure because of dilution with water. Therefore, a screening level assessment was not conducted for these occupational post application scenarios.

However, there is the potential for short- and intermediate-term post-application exposures to pine oils based on the relatively high vapor pressure. Post-application inhalation

exposure is expected for bystanders remaining in areas of treatment. At this time, air concentration measurements taken after pine oil treatments are not available. In addition, modeled results for inhalation exposure are not specific for occupational post-application uses. Therefore, the air concentration for the 80% product (diluted in water to a weight fraction of 0.009) that was used in the EFAST model estimate listed in the residential handler section above is expected to yield similar results for bystanders. The short- and intermediate-term inhalation MOE is 1,900, and therefore, not of concern (target MOE = 1,000).

e. Human Incident Data

There are some reported incidents (114 submitted cases) associated with exposure to end-use product containing pine oil. Oral, dermal, and inhalation are the primary routes of exposure. Most of the incidents are related to accidental ingestion, seven of which resulted in death. Irritation, rash, and allergic reaction have been reported with dermal exposure. Inhalation exposures cause respiratory symptoms and eye irritation and blurred vision have been reported in ocular incidents.

B. Environmental Risk Assessment

The following environmental risk characterization is intended to describe the magnitude of the estimated environmental risks associated with pine oil use. A detailed ecological hazard and environmental risk assessment for pine oil is presented in the *Ecological Hazard and Environmental Risk Assessment for Pine Oil* supporting science chapter.

1. Environmental Fate and Transport

The environmental fate assessment for pine oil is based on the Agency's Estimation Programs Interface (EPI) Suite. EPI Suite provides estimations of physical/chemical properties and environmental fate properties. Environmental fate properties of these three components are shown in Table 10. Alpha- and beta-pinene's bioconcentration factors of 2,800 (estimated) and 440 (estimated), respectively, and high log K_{ow} values suggest that bioaccumulation or bioconcentration in aquatic organisms is possible. Likewise, alpha-terpineol's bioconcentration factor of 110 suggests that a low to moderate potential for bioconcentration.

Table 10. Environmental Fate Properties of Alpha- and Beta-Pinene and Alpha-Terpineol [a]			
Parameter	**Alpha-Pinene**	**Beta-Pinene**	**Alpha-Terpineol**
Vapor Pressure @ 25C (mm Hg)	**4.75**	**2.93**	**0.0423**
Henry's Law Constant (air/water partition coefficient) (atm-cu-m/mole)	**0.107**	**0.16**	**$1.2x10^{-5}$**
KOC (organic carbon ratio in soil)	**1000**	**1200**	**1000**
Log KOW (octanol/water partition coefficient	**4.83**	**4.35**	**2.98**
BCF	**2800**	**440**	**110**

Note: a) Estimated values, from EPI Suite Program.

2. Ecological Risk

Based on the low likelihood of environmental exposure from the registered uses adverse impacts to endangered birds, mammals, fish and aquatic invertebrate species are not expected. Risk to endangered plants cannot be addressed due to a lack of phytotoxicity data; however, exposure to endangered plants is unlikely from the indoor uses of this chemical.

Table 11. Acute Oral Toxicity of Pine Oil		
Species	**Endpoint**	**Toxicity Category**
Bird		
Bobwhite quail (*Colinus virginianus*)	LD_{50} > 2,250 mg/kg NOEL = 486 mg/kg	Practically non-toxic
Mammal		
Rat	LD_{50} = 2.7 g/kg (combined)	----
Acute Ecotoxicity of Pine Oil		
Species	**Endpoints**	**Toxicity Category**
Freshwater Fish		
Rainbow trout (*Oncorhynchus mykiss*)	LC_{50} = 18.4 ppm NOEC = 10 ppm	Slightly toxic
Bluegill (*Lepomis macrochirus*)	LC_{50} = 54.8 ppm NOEC = 36 ppm	Slightly toxic
Freshwater Invertebrate		
Water flea (*Daphnia magna*)	EC_{50} = 24.5 ppm NOEC = 11 ppm	Slightly toxic

Table 11. Acute Oral Toxicity of Pine Oil		
Species	**Endpoint**	**Toxicity Category**
Other Toxicity Studies of Pine Oil		
Species	Endpoint	Toxicity Category
Subacute Dietary Toxicity		
Mallard (*Anas platyrhynchos*)	LC_{50} >5,620 ppm	Practically non-toxic
Acute Dermal Toxicity		
Rat	>2,000 mg/kg	n/a
Developmental Toxicity		
Rat	NOAEL= 50 mg/kg/day (maternal and developmental) LOAEL = 600 mg/kg/day (maternal and developmental)	n/a

1. Listed Species Consideration

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species

LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section II B, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a “no effect” determination. Based on the low likelihood of environmental exposure from the registered indoor uses, coupled with the low toxicity of pine oil to fish, aquatic invertebrates, mammals, and birds, adverse impacts to endangered birds, mammlas, fish and aquatic invertebrate species are not expected from the registered uses of pine oil. Risk to endangered plants cannot be addressed due to a lack of phytotoxicity data; however, exposure to endangered plants is unlikely from the indoor uses of this chemical. Therefore, the Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for this chemical.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

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

The Agency has completed its assessment of the dietary, occupational, drinking water and ecological risks associated with the use of pesticide products containing the active ingredient pine oil. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient pine oil, the Agency has sufficient information on the human health and ecological effects of pine oil 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 products containing pine oil 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 pine oil 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 pine oil 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 pine oil, the Agency has determined that pine oil products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of pine oil. If all changes outlined in this document are incorporated into the product labels, then all current risks for pine oil will be substantially mitigated for the purposes of this determination.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for pine oil. During the public comment period on the risk assessments, which closed on September 29, 2004, the Agency received comments from the Pine Oil Joint Venture Group. These comments in their entirety are available in the public docket, http://www.regulations.gov (EPA-HQ-OPP-2004-0302). The Joint Venture Group also submitted comments to the Agency during Phase 1, the error correction comment period. The Agency's responses to these comments are incorporated into the revised chapters and are available in the public docket.

The RED and technical supporting documents for pine oil are available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket identification (ID) number EPA-HQ-OPP-2004-0302. The public may access EPA Dockets at http://www.regulations.gov . In addition, the pine oil RED may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides reregistraion/status.htm .

C. Regulatory Position

1. Food Quality Protection Act (FQPA) Considerations

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with pine oil use. The Agency has concluded that the tolerance exemption for pine oil meets the FQPA safety standards and that the risk from dietary (food sources only) exposure is within the "risk cup." An aggregate assessment was conducted for exposures from food and residential use. The Agency has determined that the human health risks from these combined exposures are within acceptable levels provided that the mitigation contained in this document is implemented. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, water and residential exposures.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with pine oil. The Agency has determined that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of pine oil with amendments and changes as specified in this document. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of pine oil. As discussed in Chapter III, pine oil is not likely to contaminate surface and ground waters based on its use patterns and environmental fate characteristics. However, the 60% pine oil formulation shows a dietary risk of concern for chronic exposure in children.

Short, intermediate, and long-term risk typically involves exposure from dietary sources (food) in combination with residential scenarios that have a reasonable chance of co-occurrence. In the case of pine oil, residential scenarios are not felt to be long-term exposures, only short- and intermediate-term. Thus, there is no long-term aggregate risk assessment. For the short-term aggregate assessment, adult exposures from dietary sources and cleaning could be aggregated. In the case of pine oil, the dietary exposure is aggregated with the inhalation exposures from cleaning as the study and endpoint describing the effects from these two routes of exposure was the same. The dermal exposure is not included.

For toddlers, dietary exposure is aggregated with the incidental oral exposure from the floor cleaning. Although mouthing of treated clothing was assessed, this use was not specifically included in the aggregate assessment because the MOEs were so far above the target MOE that it is assumed that there is no impact on the aggregate assessment. There are no aggregate intermediate-term scenarios for toddlers, although there are intermediate-term exposure scenarios. Aggregate MOE calculations were performed using the Aggregate Risk Index method (EPA, 2001). As shown in Table 7, no aggregate risks of concern were identified for either males or females, as the ARI value is above 1 for both. However, as shown in Table 8, the ARI for children/toddlers ranges from 0.17-0.4, which is below the target ARI of ≥1, and thus, exceed the Agency's level of concern.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for pine oil, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of 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 pine oil residues in this population subgroup.

A Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from pine oil residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for pine oil based on: (1) the use of conservative NOAEL values from the developmental toxicity study for calculation of dietary and non-dietary endpoints and; (2) there is no evidence for susceptibility to exposure to pine oil from the data available. Based on the analysis of submitted developmental toxicity studies, the Agency determined that no special FQPA Safety Factor was needed since there were no residual uncertainties for pre- and/or postnatal toxicity.

d. Endocrine Disruptor Effects

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

screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

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

e. Cumulative Risks

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

2. Tolerance Summary

Pine oil (also known as 1-Methyl-4-isopropyl-1-cyclo-hexen-8-ol) (CAS No. 8002-09-3) is exempt from the requirement of a tolerance under 40 CFR 180.1035 for use in honey and beeswax. Currently there are no registered products for this use; therefore the Agency is recommending that this tolerance be revoked.

3. Codex Harmonization

No CODEX maximum residue levels (MRLs) have been established for pine oil; therefore, issues of compatibility between CODEX MRLs and U.S. tolerance do not exist.

D. Regulatory Rationale

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

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

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

The results of the dietary exposure and risk analysis indicated that of the five product formulations registered for indirect food uses, there is only one dietary exposure scenario of concern, that of children's dietary exposure to the 60 % formulation at the general cleaning concentration, where the dietary risk was estimated at 248% of the aPAD and cPAD.

To reduce residential exposure, the Agency has determined that the following mitigation is required for reregistration eligibility:

> Products with dilution rates less than 0.31% ai to have similar label language and products with the "full strength" (i.e. treatment solutions above 0.31%) dilution rates to keep that use rate, but have limited use areas. The following comments apply:

Limit the full strength or 50-50 uses on **all** pine oil labels so that it is not a general cleaner:

1. General Cleaning
   - "Use at a diluted concentration of (number) cup/gallon" (each label will be equivalent to 0.31%)
   - For spot cleaning/degreasing and/or extra tough jobs use full strength and rinse

2. Floors
   - Only use diluted general cleaning concentration for mopping floors, except bathrooms (full strength for bathrooms)
   - Spot cleaning kitchen floors with sponge or cloth at full strength with rinse

3. Disinfectant
   - Apply product to toilets, diaper pails, pet areas, etc. Spot disinfecting of counter tops or food contact areas requires a potable water rinse.
   - Rinse with water after use (on most labels already)
   - Except for spot disinfecting followed by a potable water rinse, the following use sites should be removed from the label for any use dilutions above 0.31% (3100 ppm):
     a. High chairs
     b. Tables
     c. Baby furniture (cribs, changing tables)
     d. Countertops and counters.

b. Drinking Water Risk Mitigation

Pine oil is not likely to contaminate surface and ground waters based on its use patterns. No risk mitigation measures are required to address pine oil exposure from drinking water.

c. Residential Risk Mitigation

Residential risks for handlers were calculated for short- and intermediate-term dermal and inhalation exposures. For all supported uses, residential exposure risk estimates are not of concern. Therefore, no risk mitigation measures are required to address exposure to pine oil.

d. Occupational Risk Mitigation

i. Handler Exposure

Occupational risks from handler and applicator exposures were calculated for short-term and intermediate-term dermal and inhalation exposures. The calculated MOEs indicate that aerosol-generated inhalation exposure risks are not of concern (i.e., MOEs ≥ 1,000) for short- and intermediate- term exposures under all scenarios assessed. For dermal exposure, the calculated MOEs indicate that risks do not exceed the Agency's level of concern for the low pressure spray, wiping and mopping scenarios (i.e., MOE > 100).

ii. Post-Application Risk Mitigation

Occupational post application dermal and aerosol-generated inhalation exposures to pine oil are likely to be minimal compared to handler exposure because of dilution with water. Therefore, a screening level assessment was not conducted for these occupational post application scenarios. Any residential post application exposure resulting from the occupational/commercial treatments (e.g., cleaning of day care centers) are assessed in the residential section above. The Agency does not believe that any mitigation is necessary at this time.

2. Environmental Risk Management

As the uses of pine oil considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur, no risk mitigation measures are required to address environmental exposure to pine oil.

3. 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 pine oil. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Listed Species Considerations

a. The Endangered Species Act

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for risk assessments into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

Based on the low likelihood of environmental exposure from the registered indoor uses, coupled with the low toxicity of pine oil to fish, aquatic invertebrates, mammals, and birds, adverse impacts to endangered birds, mammals, fish and aquatic invertebrate species are not expected from the registered uses of pine oil. Risk to endangered plants cannot be addressed due to a lack of phytotoxicity data; however, exposure to endangered plants is unlikely from the indoor uses of this chemical. Therefore, the Agency makes a “no effect” determination for listed species and artificial habitat based on the lack of potential exposure.

V. What Registrants Need to Do

The Agency has determined that pine oil is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 12). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For pine oil technical grade active ingredient products, the registrant needs to submit the following items:

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

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

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

Please contact ShaRon Carlisle at (703) 308-6427 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/AD)
ShaRon Carlisle
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/AD)
ShaRon Carlisle
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building),
2777 South Crystal Drive
Arlington, VA 22202

For end use products containing the active ingredient pine oil, the registrant needs to submit the following items for each product.

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

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

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

Within eight months from the receipt of the PDCI:

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

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

3. five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;

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

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

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

Please contact Adam Heyward at (703) 308-6422 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Adam Heyward
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Adam Heyward
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of pine oil has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and included in the generic DCI for this RED.

The Agency has established an interim two-tiered system for toxicology testing requirements. Tier I toxicology data requirements would apply to all indirect food additives that result in residue concentrations ranging from 0-200 ppb which applied to pine oil. The requirements would consist of an acute toxicity testing battery, subchronic toxicity study in the rodent, a developmental toxicity study in the rat, and a mutagenicity testing battery. The Agency also conducts a literature search and can also conduct a Structural Activity Relationship analysis (SAR) if appropriate. The Agency also will hold in reserve a two-generation reproduction toxicity study in the rat and a subchronic toxicity studies in a non-rodent which would become data requirements if the Agency's evaluation of the Tier 1 data warranted. A 2-generation reproduction study and a subchronic toxicity study in a non-rodent species are being held in reserve for pine oil.

Tier II studies would be triggered by the presence of significant (i.e. >200ppb) residues in food or evidence of significant toxicity from the Tier I data set, which may include developmental / reproductive, or other systemic toxicity such as presence of neoplastic growth or significant target organ toxicity. In such cases, chronic toxicity and carcinogenicity testing would be required.

As mentioned earlier, the Agency assumed that food can contact 2000 cm^2 of treated surfaces, and that 10% of the pesticide migrates to food based on the Agency Residential SOPs in its dietary risk assessment. The use of the 10% transfer rate instead of the use of a 100% transfer rate that is used in the FDA Sanitizer Solution Guidelines requires the submission of confirmatory data to establish the reliability of the use of the10% transfer rate.

The risk assessment noted deficiencies in the surrogate dermal and inhalation exposure data available from the Chemical Manufacturers Association (CMA) data base. Therefore, the Agency is requiring confirmatory data to support the uses assessed with the CMA exposure data within this risk assessment. The risk assessment also noted that many of the use parameters (e.g., amount handled and duration of use) were based on professional judgments. Therefore, descriptions of human activities associated with the uses assessed are required as confirmatory.

Table 12. Confirmatory Data Requirements for Reregistration

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Dermal Sensitization	870.2600	81-6
Dermal Indoor Exposure	875.1200, 875.1600	233 and 236
Inhalation Indoor Exposure	875.1400, 875.1600	234 and 236
Descriptions of Human Activity	875.2800	133-1
Dietary-Residues in Food from Treating Countertops with Pine Oil (FDA Wipe Study Methodology) (FDA, 2003a and 2003b)	Non-Guideline	Non-Guideline
Studies Held in Reserve		
2-Generation Reproduction	870.3800	83-4
90-day Oral Subchronic in Non-Rodents	870-3150	82-1

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 12, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

A product-specific data call-in, outlining specific data requirements, will follow 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 12.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 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 52 months from the approval of labels reflecting the mitigation described in 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.

a. 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 13. Labeling Changes Summary Table

Summary of Labeling Changes for Pine Oil		
Description	Amended Labeling Language	Placement on Label
Delete use on high chairs, baby furniture (cribs, changing tables), tables, counter tops an counters for any use dilution above 0.31% (3100ppm)		Use Directions
	Limit the full strength uses on all pine oil labels so that it is not a general cleaner	
Dilution rates less than 0.31% (0.31% (3100ppm) or less)	General Cleaning • Use at a diluted concentration of (number) cup/gallon" Floors • Only use diluted general cleaning concentration for mopping floors • Spot cleaning kitchen floors with sponge or cloth at full strength with rinse Disinfectant • Apply product to toilets, diaper pails, pet areas, etc. Spot disinfecting of counter tops or food contact areas requires a potable water rinse. • Rinse with water after use (on most labels already) • Spot disinfecting followed by a potable water rinse	Use Directions
Dilution rates above 0.31% "Full Strength"	General Cleaning • For spot cleaning/degreasing and/or extra tough jobs Floors • Only on bathroom floors • Spot cleaning kitchen floors with sponge or cloth with rinse Disinfectant • Apply product to toilets, diaper pails, pet areas, etc. Spot disinfecting of counter tops or food contact areas requires a potable water rinse. • Rinse with water after use (on most labels already) • Spot disinfecting followed by a potable water rinse - the following use sites should be removed from the label for any "full strength" dilutions (above 0.31%) a. High chairs b. Tables c. Baby furniture (cribs, changing tables) d. Countertops and counters	Use Directions

VI. APPENDICES

Appendix A: Use Patterns Eligible for Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
(1) **Agricultural premises and equipment**				
Poultry processing plant premises (nonfood contact)	soluble concentrate (EPA Reg No 2296-102, 47371-105, 47371-153, 10324-66)	Mop, sponge, swab	3 ½ tablespoons per gallon of water, 10 minute contact time	Do not use in milking stalls, parlors or milk houses. Remove all animals, poultry and feed from premises. Empty all feeding or watering appliances. Ventilate all closed spaces in which the product has been used. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent and rinse with potable water before reuse
(2) **Food handling/storage establishments premises and equipment**				
Food and Meat processing plants (non food processing areas)	soluble concentrate (EPA Reg No 45745-5, 10324-124, 6836-169, 37265-42, 34282-13, 2296-108, 8503-15, 3862-112, 47371-105, 47371-153, 4482-13, 10324-66, 491-257, 6836-168, 39272-11)	Mop, sponge, cloth, squeegee, or mechanical scrubber	4 oz – 7 ½ oz per gallon of water. 10 minute contact time.	This product is NOT to be used on food contact areas.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	soluble concentrate (EPA Reg No 6836-177)	Mop, sponge, cloth, squeegee, or mechanical scrubber	1 1/3 oz per two gallons of water. 10 minute contact time	This product is NOT to be used on food contact areas.
Eating Establishments (non food processing areas)	soluble concentrate (EPA Reg No 45745-5, 10324-124, 6836-169, 37265-42, 34282-13, 2296-108, 8503-15, 70799-1, 4170-8, 3862-112, 4482-13, 39272-11)	Mop, sponge, cloth, squeegee, or mechanical scrubber	4oz per gallon of water for disinfection.	This product is NOT to be used on food contact areas.
	soluble concentrate (EPA Reg No 4313-41, 6836-177)	Mop or spray	1 ½ - 1 1/3 oz per gallon of water, 10 minute contact time to disinfect	All treated food contact areas must be scrubbed with detergent and rinsed with potable water before use.
(3) **Commercial, institutional and industrial premises and equipment**				
Commercial and institutional, non-porous surfaces	soluble concentrate (EPA Reg No 99-24 45745-5, 10324-124, 6836-169, 37265-42, 2296-108, 2296-102, 8503-15, 70799-1, 9886-13, 9886-14, 1672-14, 777-75, 4170-8, 3862-112, 47371-105,	Mop, sponge, cloth, squeegee, or mechanical scrubber	2 - 5oz per gallon of water for disinfection.	This product is NOT to be used on food contact areas. Rinse with potable water when used on rubber or asphalt tile

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	47371-153, 11668-10, 4482-13, 6836-87, 10324-66, 11668-17, 5813-36, 2296-105, 72138-5, 5813-28, 8730-6, 47371-105, 3862-11, 3862-10, 24909-15, 2230-57, 72138-1)			
	soluble concentrate (EPA Reg No 4313-41, 6836-177)	Mop, sponge, cloth, squeegee, or mechanical scrubber	1 ½ - 1 1/3 oz per gallon of water, 10 minute contact time to disinfect	All treated food contact areas must be scrubbed with detergent and rinsed with potable water before use.
Commercial floors	soluble concentrate (EPA Reg No 47371-102, 47371-105, 70799-1, 34160-5, 3862-11, 3862-10, 2296-104, 34160-1, 11668-13, 72138-1, 72138-6)	Mop, sponge, cloth, squeegee, or mechanical scrubber	2 – 4 oz per gallon	Must rinse no wax floors
Schools (hard non porous surfaces)	soluble concentrate (EPA Reg No 2296-102, 4313-41, 45745-5, 6836-169, 37265-42, 70799-1, 1672-14, 3862-112, 4482-13, 6836-87, 10324-66, 2296-105, 6836-169, 2230-57, 72138-6)	Mop, sponge, cloth, squeegee, spray or mechanical scrubber	3 ½ tablespoons - 5oz per gallon of water, 10 minute contact time	Following application as a low or high pressure spray, do not enter treated area until sprays have dried. All treated food contact areas must be scrubbed with detergent and rinsed with potable water before use.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	soluble concentrate (EPA Reg 6836-177)	Mop, sponge, cloth, squeegee, or mechanical scrubber	1 1/3 oz per gallon of water, 10 minute contact time to disinfect	All treated food contact areas must be scrubbed with detergent and rinsed with potable water before use.
Refuse/solid waste containers (garbage cans)	soluble concentrate (EPA Reg No 99-24, 2296-102, 6836-177, 34282-13, 70799-1, 9886-13, 9886-14, 3862-136, 777-75, 47371-105, 47371-153, 4482-13, 72138-6)	Wetting solution	1 ¾ - 6 oz per gallon of water. Rinse empty can with the solution	
	soluble concentrate (EPA Reg No 45745-5, 10324-124, 6836-169, 37265-42, 34282-13, 2296-108, 8503-15, 4170-8, 3862-112, 11668-17, 39272-11)	Wetting solution	16oz of product per gallon of water	It is especially important to preclean for the product to work properly
Refuse/solid waste transportation facilities/handling equipment	soluble concentrate (EPA Reg No 45745-5, 6836-169, 37265-42, 34282-13, 2296-108, 8503-15)	Wetting Solution	16oz of product per gallon of water	It is especially important to preclean for the product to work properly
	soluble concentrate	Mop, sponge, cloth,	1 1/3 - 2 oz per two	All treated food contact areas

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	(EPA Reg 6836-177, 65595-1)	squeegee, or mechanical scrubber	gallons of water, 10 minute contact time to disinfect	must be scrubbed with detergent and rinsed with potable water before use.
Public Transportation and facilities	soluble concentrate (EPA Reg No 4313-41, 1839-112, 6836-177)	Mop, sponge, swab or spray	1 ½ - 4 oz per gallon of water, 10 minute contact time to disinfect	Following application as a low or high pressure spray, do not enter treated area until sprays have dried. All treated food contact areas must be scrubbed with detergent and rinsed with potable water before use.
(4) **Residential and public access premises**				
Household/Domestic dwellings indoor nonfood handling areas	soluble concentrate (EPA Reg No 99-24, 2296-102, 45745-5, 6836-169, 65595-1, 70799-1, 9886-13, 9886-14, 777-75, 4170-8, 3862-112, 5813-33, 47371-105, 47371-153, 11668-10, 4482-13, 5813-36, 5813-31, 2296-105, 72138-5, 5813-28, 5813-54, 5813-56, 5813-30, 3573-50, 81260-1, 49547-10, 2230-57, 11668-13)	Mop, sponge, cloth, squeegee, or mechanical scrubber	3 ½ tablespoons - 4oz per gallon of water, 10 minute contact time	This product is NOT to be used on food contact areas. Without a potable water rinse.
Residential Floors	soluble concentrate (EPA Reg No 3573-50, 49827-7,	Mop, sponge, cloth, squeegee, or mechanical	2 – 4 oz per gallon	Must rinse no wax floors

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	5813-37)	scrubber		
Animal kennels/Sleeping quarters (commercial)	soluble concentrate (EPA Reg No 6836-169, 9886-13, 9886-14, 4170-8, 4482-13, 2230-57)	Mop, sponge, cloth, squeegee, or mechanical scrubber	4 – 7 ½ oz per gallon of water for disinfection. 10 minute contact time.	This product is NOT to be used on food contact areas.
Pet Living/sleeping quarters	soluble concentrate (EPA Reg No 5813-33, 5813-36, 5813-28, 5813-54, 5813-56, 4313-9, 72138-3, 72138-2, 72138-4, 2230-57, 72138-1)	Mop, sponge, swab	3 ½ tablespoons - 4oz per gallon of water, 10 minute contact time	Use fresh solution each day
Dog Baths	soluble concentrate (EPA Reg No 8848-11, 9886-12, 9886-19, 9886-17, 9886-16)	Sponge or swab	1 ¾ oz per gallon of water	
Horse Baths	soluble concentrate (EPA Reg No 11715-290	Sponge or spray	18.28 oz per gallon	Do not get in animals eyes
Cars, Campers and Boats (interior surfaces)	Ready to use spray, soluble concentrate (EPA Reg 5813-37, 5138-34)	Spray, mop, sponge, swab	Spray until thoroughly wet/add ½ per gallon	
Taxis, buses, trains (interior surfaces)	soluble concentrate (EPA Reg 6836-168,	Mop, sponge, cloth, squeegee, or	1 ¼ - 4 oz per gallon, 10 minute contact time	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	6836-169, 6836-177)	mechanical scrubber		
Bathroom premises	soluble concentrate (EPA Reg No 99-24, 2296-102, 10324-124, 45745-5, 6836-169, 37265-42, 34282-13, 65595-1, 2296-108, 8503-15, 70799-1, 9886-13, 9886-14, 3862-136, 1672-14, 777-75, 3862-112, 5813-33, 47371-105, 47371-153, 11668-10, 4482-13, 6836-87, 11668-17, 5813-36, 5813-31, 2296-105, 72138-5, 5813-28, 5813-54, 5813-56, 5813-30, 5741-16, 70799-1, 24909-15, 34160-1, 81260-1, 49547-10, 2230-57, 11668-13, 39272-11, 72138-6)	Mop, sponge, swab	3 ½ tablespoons - 4oz per gallon of water, 10 minute contact time	Use fresh solution each day
	soluble concentrate (EPA Reg No 4313-41, 3862-136)	Mop, sponge, swab or spray	1 ½ oz per gallon of water, 10 minute contact time to disinfect	Following application as a low or high pressure spray, do not enter treated area until sprays have dried. All treated food contact areas must be scrubbed with detergent and rinsed with potable water before use.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Urinals (interior surfaces)	soluble concentrate (EPA Reg No 2296-102, 4313-41, 6836-169, 70799-1, 9886-13, 9886-14, 3862-136, 11668-10, 4482-13, 11668-17, 5813-36, 5813-31, 2296-105, 72138-5, 5813-28, 5813-54, 5813-56, 5813-30, 10807-111, 777-60, 72138-6)	Mop, sponge, swab	2 - 4 tablespoons per gallon of water, 10 minute contact time	
Urinals (interior surfaces)	soluble concentrate, ready to use liquid (EPA Reg No 47371-153)	Mop, sponge, swab	Add 3 - 6 oz directly to bowl	
Diaper Pails	soluble concentrate (EPA Reg No 5813-33, 5813-36, 5813-28, 5813-54, 5813-56, 10807-111, 777-60)	Mop, sponge, swab	3 ½ tablespoons - 4oz per gallon of water, 10 minute contact time	Use fresh solution each day
Diapers (pre soak)	soluble concentrate (EPA Reg No 11668-10, 5813-31, 5813-30, 8848-11)	Soaking solution	1 – 4 oz per gallon	Use fresh solution each day

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
(5) **Medical premises and equipment**				
Barber/beauty shop equipment and premises	soluble concentrate (EPA Reg No 45745-5, 10324-124, 6836-169, 37265-42, 34282-13, 2296-108, 8503-15, 4170-8, 3862-112, 10807-111, 39272-11)	Mop, sponge, swab	4 – 7 ½ oz per gallon of water for disinfection. 10 minute contact time.	This product is NOT to be used on food contact areas. Product in NOT to be used as a high level disinfectant/sterilant on critical or semi-critical items. Product may be used to preclean or decontaminate semi-critical and critical items prior to sterilization or high level disinfection.
Hospital/medial institutions, non-critical premises	soluble concentrate (EPA Reg No 45745-5, 10324-124, 6836-169, 37265-42, 34282-13, 2296-108, 8503-15, 1672-14, 777-75, 4170-8, 3862-112, 4482-13, 6836-87, 10324-66, 572-5, 2296-104, 24909-15)	Mop, sponge, swab	4 – 8 oz per gallon of water for disinfection.	This product is NOT to be used on food contact areas. Product in NOT to be used as a high level disinfectant/sterilant on critical or semi-critical items. Product may be used to preclean or decontaminate semi-critical and critical items prior to sterilization or high level disinfection.
Veterinary Clinics, non-critical premises	soluble concentrate (EPA Reg No 45745-5, 10324-124, 6836-169, 37265-42, 34282-13, 2296-108, 8503-15,	Mop, sponge, swab	4 – 7 ½ oz per gallon of water for disinfection. 10 minute contact time.	This product is NOT to be used on food contact areas. Product in NOT to be used as a high level disinfectant/sterilant on critical or semi-critical items. Product may be used to

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	3862-112, 6836-169)			preclean or decontaminate semi-critical and critical items prior to sterilization or high level disinfection.
Laundry (Hospital)	soluble concentrate (EPA Reg No 99-24)	Soaking solution	6 tablespoons to one gallon of water	Soak clothing and bedclothes before laundering
	soluble concentrate (EPA Reg No 11668-10, 11668-17, 5813-36, 5813-31, 72138-5, 5813-54, 5813-56, 5813-30, 72138-1, 72138-8, 8848-11, 9886-12, 9886-19, 9886-17, 9886-16, 34160-5, 49827-2, 81260-1, 49547-10, 777-60, 72138-1)	Directly into laundry machine	½ to 1 cup per load in the laundry	

APPENDIX B: Pine Oil (Case 3113)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Pine Oil. These requirements apply to Pine Oil in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

2. **Guideline Description** (Column 3). Identifies the guideline type.

3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

   (1) Agricultural premises and equipment
   (2) Food handling/ storage establishments premises and equipment
   (3) Commercial, institutional and industrial premises and equipment
   (4) Residential and public access premises
   (5) Medical premises and equipment
   (6) Human water systems
   (7) Materials preservatives
   (8) Industrial processes and water systems
   (9) Antifouling coatings
   (10) Wood preservatives
   (11) Swimming pools
   (12) Aquatic areas

4. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

GENERIC DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
CHEMISTRY (TECHNICAL GRADE ACTIVE INGREDIENT (TGAI)				
830.1550	61-1	Product Identity and Composition	2,3,4,5	41771401; 40872201; 41769701; 41759901; 41882101; 41765101
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	2,3,4,5	41771401; 40872201; 41769701;41759901; 41765101; 41882101
830.1670	61-2b	Formation of Impurities	2,3,4,5	41771401; 40872201; 41769701; 41759901; 41765101; 41882101
830.1700	62-1	Preliminary Analysis	2,3,4,5	41771402; 42294002;41759902; 42276301; 41765102; 42259901; 41882102; 42189404
830.1750	62-2	Certification of Limits	2,3,4,5	41771402; 42294002; 41759902; 42276301; 41882102; 41765102; 42259901; 41884002
830.1800	62-3	Analytical Method	2,3,4,5	41771402; 42294002; 41759902; 42276301; 41765102; 42259901
830.6302	63-2	Color	2,3,4,5	40872203; 42189402
830.6303	63-3	Physical State	2,3,4,5	42189402
830.6304	63-4	Odor	2,3,4,5	40872203; 42189402
830.7200	63-5	Melting Point	2,3,4,5	42189402; 42189402
830.7220	63-6	Boiling Point	2,3,4,5	42189402; 40872203
830.7300	63-7	Density	2,3,4,5	42189402; 40872203
830.7840 830.7860	63-8	Solubility	2,3,4,5 2,3,4,5	42189402; 40872203

GENERIC DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7950	63-9	Vapor Pressure	2,3,4,5	42189402; 40872203
830.7370	63-10	Dissociation Constant in Water	2,3,4,5	42189402
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	2,3,4,5	42189402; 40872203
830.7000	63-12	pH	2,3,4,5	42189402
830.6313	63-13	Stability	2,3,4,5	42189402; 40872203
830.6314	63-14	Oxidizing/Reducing Action	2,3,4,5	Not required
830.6315	63-15	Flammability	2,3,4,5	Not required/
830.6316	63-16	Explodability	2,3,4,5	Not required
830.6317	63-17	Storage Stability	2,3,4,5	Not required
830.7100	63-18	Viscosity	2,3,4,5	Not required
830.6319	63-19	Miscibility	2,3,4,5	Not required
830.6320	63-20	Corrosion Characteristics	2,3,4,5	Not required
830.6321	63-21	Dielectric breakdown voltage	2,3,4,5	Not required
ECOLOGICAL EFFECTS				
850.2100	71-1a	Avian Acute Oral Toxicity Test - Quail/duck	2,3,4,5	43375201
850.2200	71-2a	Acute Avian Dietary - Quail	2,3,4,5	43375203
850.2200	71-2b	Acute Avian Dietary - Duck	2,3,4,5	43375204
850.1075	72-1a	Fish Toxicity - Bluegill	2,3,4,5	43375205
850.1075	72-1c	Fish Acute Toxicity - Rainbow Trout	2,3,4,5	43375206
850.1010	72-2a	Acute Aquatic Invertebrate Toxicity	2,3,4,5	43375207

GENERIC DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	2,3,4,5	40253502
870.1200	81-2	Acute Dermal - Rabbit	2,3,4,5	40253503
870.1300	81-3	Acute Inhalation - Rat	2,3,4,5	43375208
870.2400	81-4	Acute Eye Irritation - Rabbit	2,3,4,5	43375209
870.2500	81-5	Acute Skin Irritation - Rabbit	2,3,4,5	43375210
870.2600	81-6	Dermal Sensitization	2,3,4,5	43375211, Unacceptable, Data Gap
870.6200	81-7	Neurotoxicity Study - Hens	2,3,4,5	Not required
870.3100*	82-1a	90-Day Oral Subchronic -Rat	2,3,4,5	Required, Data Gap (Held In Reserve)
870.3150	82-1b	90-Day Oral Subchronic - Non Rodent	2,3,4,5	Not required
870.3250	82-3	90-Day Dermal Subchronic - Rat	2,3,4,5	40515401; 40515201
870.3465	82-4	9-Day Subchronic Inhalation	2,3,4,5	Not required
870.6200*	82-7	90-Day Oral Neurotoxicity - Rat	2,3,4,5	Required, Data Gap
870.4100	83-1a	Chronic Toxicity - rat	2,3,4,5	Not required
870.4100	83-1b	Chronic Toxicity - non-rodent	2,3,4,5	Not required
870.4200	83-2a	Oncogenicity - rat	2,3,4,5	Not required
870.4200	83-2b	Oncogenicity - mouse	2,3,4,5	Not required
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity - rat	2,3,4,5	Not required
870.3700	83-3a	Prenatal Developmental Toxicity - Rat	2,3,4,5	40515201
870.3700	83-3b	Prenatal Developmental Toxicity - Rabbit	2,3,4,5	Not required

GENERIC DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.3800	83-4	Reproduction and fertility effects - Rat	2,3,4,5	Required, Data Gap
870.5100	84-2a	Bacterial Reverse Mutation Test	2,3,4,5	43375212
870.5375	84-2b	In Vitro Mammalian Chromosome Aberration Test	2,3,4,5	40341403, Unacceptable, Data Gap
870.5550	84-4	Other genotoxic effects	2,3,4,5	40341404
870.7485	85-1	Metabolism and Pharmacokinetics	2,3,4,5	Not Required
870.7600	85-2	Dermal Penetration	2,3,4,5	Not required
*The data requirements for a 90-day oral subchronic toxicity study in the rat and a 90-day oral neurotoxicity study in the rat can be fulfilled by a 90-day oral subchronic toxicity study in the rat with additional neurotoxicity parameters [special (combined) study: OPPTS 870.3100 and OPPTS 870.6200].				
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.1200 875.1600	233, 236	Dermal Indoor Exposure	2,3,4,5	Confirmatory, Data Gap
875.1400 875.1600	234, 236	Inhalation Indoor Exposure	2,3,4,5	Confirmatory, Data Gap
875.2800	133-1	Descriptions of Human Activity	2,3,4,5	Confirmatory, Data Gap
Non-Guideline	Non-Guideline	Dietary-Residues in Food from Treating Countertops with Pine Oil (FDA Wipe Study Methodology) (FDA, 2003a and 2003b)	2,3,4,5	Confirmatory, Data Gap
ENVIRONMENTAL FATE				
None	160-5	Chemical Identity	2,3,4,5	41771401; 40872201; 42294002 41765101; 41882101; 41884001
None	161-1	Hydrolysis of Parent and Degradates	2,3,4,5	Not required
None	171-2	Chemical Identity	2,3,4,5	41771401; 40872201; 41882101 41884001

GENERIC DATA REQUIREMENTS				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
None	171-3	Chemical Identity	2,3,4,5	41771401; 40872201

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket located in Room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the draft risk assessments and related documents as of September 17, 2004 The EPA then considered all comments and revised the risk assessments.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov, docket ID # **EPA-HQ-OPP-2004-0302.**

These documents include:

- Pine Oil Preliminary Risk Assessment, 9/17/04
- Revised Pine Oil Risk Assessment, 1/26/2006
- Pine Oil- Report of the Antimicrobials Division Toxicology Endpoint Selection Committee. Antimicrobials Division, 5/20/04, Timothy F. McMahon, Ph.D., Chair, ADTC
- Product Chemistry Science Chapter. Antimicrobials Division, 1/21/04 , A. Najm Shamim, Ph.D., Chemist
- Environmental Fate Studies and Environmental Fate Assessment. Antimicrobials Division, 4/27/04, A. Najm Shamim, Ph.D.
- Dietary Assessment. Antimicrobials Division, 9/22/04, A. Najm Shamim, Ph.D.
- Toxicology Disciplinary Chapter. Antimicrobials Division, 9/8/04, Timothy F. McMahon, Ph.D
- Occupational and Residential Exposure. Antimicrobials Division, 9/8/04, Timothy Leighton, Environmental Scientist
- Revised Occupational and Residential Exposure ore Addendum. Antimicrobials Division, 6/26/06, Cassi Walls, Ph.D
- Ecological Hazard and Environmental Risk Characterization. Antimicrobials Division, 9/8/04, Kathryn Montague, M.S.
- Incident Reports Associated with Pine Oil. Antimicrobials Division, 8/3/04, Jonathan Chen, PhD

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 Pine Oil 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.

1. MRID Studies

MRID 40253502. Naas, D. (1987) Acute Oral Toxicity (LD50) Study in Albino Rats with Pine Oil Blend CSMA 1687: Final Report: Project No. WIL- 114001. Unpublished study prepared by WIL Research Laboratories, Inc. 62 p.

MRID 40253503. Naas, D. (1987) Acute Dermal Toxicity (LD50) Study in Albino Rabbits with Pine Oil Blend CSMA 1687: Final Report: Project No. WIL-114002. Unpublished study prepared by WIL Research Laboratories, Inc. 34 p.

MRID 40341402. Yang, L. (1987) CHO/HGPRT Mutation Assay: Pine Oil Blend, CSMA 1687: Lab. Study No. T5366.332001. Unpublished study prepared by Microbiological Associates Inc. 29 p.

MRID 40341403. Putman, D. (1987) Micronucleus Cytogenetic Assay in Mice: Pine Oil Blend, CSMA 1687: Final Report: Study No. T5366.122. Unpublished study prepared by Microbiological Associates, Inc. 25 p.

MRID 40341404. Curren, R. (1987) Unscheduled DNA Synthesis in Rat Primary Hepatocytes with a Confirmatory Assay: Pine Oil Blend, CSMA 1687: Final Report: Study No.T5366.380016. Unpublished study prepared by Microbiological Associates, Inc. 30 p.

MRID 40515201. Dearlove, G. (1988) Developmental Toxicity (Embryo/Fetal Toxicity and Teratogenic Potential) Study of Pine Oil Blend 1687 Administered Orally via Gavage to Crl:CD (SD)BR Presumed Pregnant Rats: Argus Research Laboratories, Inc. Protocol 603-002: CSMA 10-9. Unpublished study prepared by Argus Research Laboratories, Inc. 323 p.

MRID 40515401. Naas, D. (1988) 90 Day Dermal Toxicity Study in Rats with Pine Oil Blend CSMA 1687: Laboratory Project No. WIL-114006. Unpublished study performed by WIL Research Laboratories, Inc. 760 p.

MRID 40872201. American Cyanamid Co. (1988) Product Identity and Composition of Cyanamid Pine Oil|. Unpublished study. 9 p.

MRID 40872203. American Cyanamid Co. (1988) Physical and Chemical Characteristics: Cyanamid Pine Oil. Unpublished study. 8 p.

MRID 41759901. T & R Chemicals, Inc. (1991) Preliminary Analysis, Certified Limits and Enforcement Analytical Methodology for T & R El Pinol 80: Interim Report: Lab Project Number: 90-GR-0003. Unpublished study prepared by Toxikon Corp. 26 p.

MRID 41759902. T & R Chemicals, Inc. (1991) Preliminary Analysis, Certified Limits and Enforcement Methodology for T & R Chemicals, Inc.: Interim Report: Lab Project Number: 90-GR-0003. Unpublished study pre- pared by T & R Chemicals, Inc. 312 p.

MRID 41765101. Davis, K.; Batey, J. (1991) Product Chemistry Data of Glidco Pine Oil 80. Unpublished study prepared by SCM Glidco Organics. 78 p.

MRID 41765102. Lynn, S. (1991) Interim Report: Preliminary Analysis, Certified Limits and Enforcement Analytical Methodology of Glidco Pine Oil 80: Lab Project Number: 90-GR-0006. Unpublished study prepared by Toxikon Corp. 323 p.

MRID 41769701. Baker, R. (1991) Product Chemistry Data of Unipine 80. Unpublished study prepared by Union Camp Corp. 309 p.

MRID 41771401. Rohl, A. (1991) Product Chemistry Data of Herco Pine Oil: EPA Reg- istration Number 891-175: Lab Project Number: 891-175. Unpublished study prepared by Hercules Inc. 58 p.

MRID 41771402. Lynn, S. (1991) Interim Report: Preliminary Analysis, Certified Limits and Enforcement Analytical Methodology of Herco Pine Oil Lab Project Number: 891-175. Unpublished study prepared by Toxikon Inc. 340 p.

MRID 41882101. Johnson, C. (1991) Product Chemistry Data of Arizole Pine Oil 80: Lab Project Number: 39055-2. Unpublished study prepared by Ari- zona Chemical Co. 35 p.

MRID 41882102. Lynn, S. (1991) Interim Report: Preliminary Analysis, Certified Limits and Enforcement Methodology of Arizole Pine Oil 80: Lab Project Number: 90-GR-0007. Unpublished study prepared by Toxikon Corp. 293 p.

MRID 41884001. Johnson, C. (1991) Product Chemistry Data of Arizole Pine Oil: Lab Project Number: 39055-1. Unpublished study prepared by Arizona Chemical Co. 35 p.
MRID 42189401. Davis, K. (1992) Product Chemistry Data of CSMA Composite Sample 110990: Lab Project Number: CSM/COMP61. Unpublished study prepared by RegWest Co. 35 p.

MRID 42189402. Desai, L. (1992) Physical and Chemical Characteristics of CSMA Composite Sample 110990: Lab Project Number: 91-GR-0032. Unpublished study prepared by Toxicon Corp. 168 p.

MRID 42189403. Desai, L. (1992) Purity Analysis of Internal Source Standards: gamma-Terpinol, beta-Terpinol, 1,4-Cineole and para-Mentha 2,4(8)-diene: Lab Project Number: 91-GR-0015. Unpublished study prepared by Toxicon Corp. 57 p.

MRID 42189404. Batey, J. (1992) Preliminary Analysis: Area Normalization Percentages of CSMA Composite Sample 110990: Lab Project Number: 39-156H. Unpublished study prepared by Toxicon Corp. 34 p.

MRID 42259901. Batey, J. (1992) Preliminary Analysis: Area Normalization Percentages of Glidco Pine Oil 80: An Amendment: Lab Project Number: 39-156A. Unpublished study prepared by SCM Glidco Organics. 38 p.

MRID 42276301. Batey, J. (1992) Preliminary Analysis: Area Normalization Percentages of El Pinol 80: Lab Project Number: 39-156G. Unpublished study prepared by SCM Glidco Organics. 35 p.

MRID 42294002. Batey, J. (1992) Preliminary Analysis: Area Normalization Percentages of Unipine 80: Lab Project Number: 39-156B. Unpublished study prepared by SCM Glidco Organics. 37 p.

MRID 43375201. Campbell, S.; Beavers, J. (1994) Pine Oil: Acute Oral Toxicity Study with the Northern Bobwhite: Lab Project Number: 274-104. Unpublished study prepared by Wildlife International Ltd. 20 p.

MRID 43375202. Campbell, S.; Beavers, J. (1994) Pine Oil: Acute Oral Toxicity Study with the Mallard: Lab Project Number: 274-105. Unpublished study prepared by Wildlife International Ltd. 21 p.

MRID 43375204. Campbell, S.M. and J.B. Beavers. 1994. Pine oil: Dietary LC50 study with the Mallard. August 31, 1994. Wildlife International Ltd., Laboratory Report ID: 274-103.

MRID 43375205. Graves, W.C. and J.P. Swigert. 1994. Pine oil: Ninety-six hour flow-through acute toxicity test with the Bluegill (*Lepomis macrochirus*). August 19, 1994. Wildlife International Ltd., Laboratory Report ID: 274A-101. .

MRID 43375206. Graves, W.; Swigert, J. (1994) Pine Oil: Ninety-six (96) Hour Flow-through Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss): Lab Project Number: 274A-102. Unpublished study prepared by Wildlife International Ltd. 46 p.

MRID 43375207. Graves, W.; Swigert, J. (1994) Pine Oil: Forty-eight (48) Hour Flow-through Acute Toxicity Test with the Cladoceran (Daphnia magna): Lab Project Number: 274A-103. Unpublished study prepared by Wildlife International Ltd. 45 p.

MRID 43375208. Robbins, G. (1994) Pine Oil: Acute Inhalation Toxicity Study in Rats: Lab Project Number: C3371. Unpublished study prepared by Cosmopolitan Safety Evaluations, Inc. 35 p.

MRID 43375209. Robbins, G. (1994) Pine Oil: Primary Eye Irritation Study in Rabbits: Lab Project Number: D3371. Unpublished study prepared by Cosmopolitan Safety Evaluations, Inc. 28 p.

MRID 43375210. Robbins, G. (1994) Pine Oil: Primary Dermal Irritation Study in Rabbits: Lab Project Number: E3371. Unpublished study prepared by Cosmopolitan Safety Evaluations, Inc. 18 p.

MRID 43375211. Robbins, G. (1994) Pine Oil: Dermal Sensitization (Buehler) in Guinea Pigs: Lab Project Number: F3371. Unpublished study prepared by Cosmopolitan Safety Evaluations, Inc. 44 p.

MRID 43375212. Ferrante, S. (1994) Pine Oil: Salmonella typhimurium Reverse Mutation Assay: Lab Project Number: 94G-0332. Unpublished study prepared by Toxikon Corp. 31 p.

2. Supporting Documentation

EPI Suite, Version 3.12. http://www.epa.gov/opptintr/exposure/docs/updates_episuitedl.htm

USEPA. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Contract No. 68-W6-0030. Prepared by the Residential Exposure Assessment Work Group. Office of Pesticide Programs, Health Effects Division and Versar. July 1997.

USEPA. 1997. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.

USEPA, 1997. "Exposure Factors Handbook, Vol III: Activity Factors." EPA/600/P-95/002FC

USEPA, 1997. "Exposure Factors Handbook, Vol III: Activity Factors." EPA/600/P-95/002FC

USEPA, 1999. " Available Information on Assessing Exposure from Pesticides, A User's Guide, http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/p17493.htm

USEPA, 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. Memorandum from Siroos Mostaghimi, Ph.D., USEPA, to Julie Fairfax, USEPA. Dated November 4, 1999. DP Barcode D247642.

USEPA. 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. Memorandum from Siroos Mostaghimi, Ph.D., USEPA, to Julie Fairfax, USEPA. Dated November 4, 1999. DP Barcode D247642.

USEPA, 1999. "Available Information on Assessing Exposure from Pesticides, A User's Guide, http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/p17493.htmHttp://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061,

USEPA, 2000. Residential SOPs. EPA Office of Pesticide Programs–Human Health Division. Dated April 5, 2000.

USEPA, 2000. Residential SOPs. EPA Office of Pesticide Programs–Human Health Division. Dated April 5, 2000.

USEPA, 2002. Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment. Office of Pesticide Programs, February 2002.

USEPA, 2002. Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment. Office of Pesticide Programs, February 2002.

USEPA, 2002. ECOTOX User Guide: ECOTOXicology Database System. Version 3.0. Available:http://www.epa.gov/ecotox/

U.S. Environmental Protection Agency (EPA). 2002. ECOTOX User Guide: ECOTOXicology Database System. Version 3.0. Available: http://www.epa.gov/ecotox/

FDA, 2003. " Sanitizing Solutions: Chemistry Guidelines for Food Additive Petition.", January 1993 version., http://www.cfsan.fda.gov/~dms/opa-cg3a.html.

FDA, 2003. " Sanitizing Solutions: Chemistry Guidelines for Food Additive Petition.", January, 1993 version http://www.cfsan.fda.gov/~dms/opa-cg3a.html

Hazard Substances Databank (HSDB), A Database of the National Library of Medicine's TOXNET System.

Hazard Substances Databank (HSDB), A Database of the National Library of Medicine's TOXNET System.

3. Open Literature

Bonfiglio, JF; Hintze KL.; and Siegell, LT. 1987. A Multi-Center Evaluation of the Incidence and Severity of Pine-Oil Ingestion. Presented in the meeting of the American Academy of Clinical Toxicity, American Association of Poison Control Centers, American Booard of Medical Technology, Canadian Association of Poison Control Centers, Vancouver, British Columbia, Canada. September27- October 2, 1987. Abstract published in Vet. Hum. Toxicol. 29(6): 481.

Brook, M.; McCarron, M.; and Mueller, JA. 1989. Pine Oil Cleaner Ingestion. Annals of Emergency Medicine. 18:391-395

Welker, JA and Zaloga, GP. 1999. Pine Oil Ingestion - A Common Cause of Poisoning. Chest: 1822-1826.

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Pine Oil RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. Batching of Pine Oil 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 pine oil as an 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), and labeling (e.g., signal word, use classification, precautionary labeling). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

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

data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

If a registrant would like to have the batching status of a product reconsidered, he/she needs to submit detailed information on the product, including a detailed rationale for the inclusion of the product into a batch. An MSDS for each "inert" ingredient should be included where possible. However, registrants and manufacturers should realize that the more unusual their formulation is, the less likely it is to be able to batch that product.

Eighty-nine products were found which contain pine oil as an active ingredient. These products have been placed into ten batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. Any product in a batch may cite new or previously submitted acute toxicity data (if it meets current Agency standards) from any other product in the same batch, except as specified below:

- Batch 1: Each product must cite its own data or data from any other product in the batch.

- Batch 2: Each product must cite its own data or data from one of the 80% pine oil products in the batch. For eye irritation data, however, each product with pH above 11.0 must cite its own data.[1]

- Batch 3: Each product must cite its own data or data from Reg. No. 9886-13, 11668-13, or 34160-5. For eye irritation data, however, each product with pH above 11.0 must cite its own data.[1]

- Batch 4: Each product must cite its own data or data from one of the 30% pine oil products in the batch. For eye irritation data, however, each product with pH above 11.0 must cite its own data.[1]

- Batch 5: Each product must cite its own data or data from Reg. No. 9886-16, 9886-17, 11668-17, or 72138-3. For eye irritation data, however, each product with pH above 11.0 must cite its own data.[1]

- Batch 6: Each product must cite its own data or data from Reg. No. 5813-36.

- Batch 7: Each product must cite its own data or data from Reg. No. 3862-11. For eye irritation data, however, each product must cite its own data.

- Batch 8: Each product must cite its own data or data from any other product in the batch. For eye irritation data, however, Reg. No. 6836-87 must cite its own data, and the other products may *not* cite that data.

- Batch 9: Each product must cite its own data or data from Reg. No. 5813-31.

- Batch 10: Each product must cite its own data or data from any other product in the batch.

· No Batch: Each product in this category must cite its own data.

Batch 1	EPA Reg. No.	% Active Ingredient
Each Batch 1 product must cite its own data or data from any other product in the batch.	891-174	99.5%
	891-175	99.5%
	891-176	99.5%
	891-181	99.5%
	5813-41	99%
	9886-2	100%
	9886-4	100%
	9886-7	100%
	9886-9	100%
	9886-10	100%
	11668-3	99.5%
	39055-1	100%
	49547-4	100%
	49547-5	100%

Batch 2	EPA Reg. No.	% Active Ingredient
Each Batch 2 product must cite its own data or data from one of the 80% pine oil products in the batch. For eye irritation data, however, each product with pH above 11.0 must cite its own data.[1]	99-24	73%
	572-5	70%
	2296-104	70%
	3862-10	80%
	4313-9	80%
	9886-14	80%
	34160-1	80%
	70799-1	78.2%
	72138-5	80%

Batch 3	EPA Reg. No.	% Active Ingredient

Each Batch 3 product must cite its own data or data from Reg. No. 9886-13, 11668-13, or 34160-5. For eye irritation data, however, each product with pH above 11.0 must cite its own data.[1]	8848-11	50%
	9886-13	60%
	11668-13	60%
	34160-5	62%

Batch 4	EPA Reg. No.	% Active Ingredient
Each Batch 4 product must cite its own data or data from one of the 30% pine oil products in the batch. For eye irritation data, however, each product with pH above 11.0 must cite its own data.[1]	5813-28	30%
	9886-12	30%
	9886-19	25%
	11668-10	30%
	72138-1	30%
	72138-2	25%

Batch 5	EPA Reg. No.	% Active Ingredient
Each Batch 5 product must cite its own data or data from Reg. No. 9886-16, 9886-17, 11668-17, or 72138-3. For eye irritation data, however, each product with pH above 11.0 must cite its own data.[1]	5813-33	21.8%
	9886-16	19.9%
	9886-17	19.9%
	11668-17	19.9%
	62644-1	19.9%
	72138-3	20%
	72138-8	15%

Batch 6	EPA Reg. No.	% Active Ingredient
Each Batch 6 product must cite its own data or data from Reg. No. 5813-36.	5813-36	19%
	5813-54	15%

Batch 7	EPA Reg. No.	% Active Ingredient
Each Batch 7 product must cite its own data or data from Reg. No. 3862-11. For eye irritation data, however, each product must cite its own data.	3862-11	Pine oil 17.3% Sodium 2-benzyl-4-chlorophenate 5.1%
	3862-136	Pine oil 13.54% Sodium 2-benzyl-4-chlorophenate 3.93%

Batch 8	EPA Reg. No.	% Active Ingredient
Each Batch 8 product must cite its own data or data from any other product in the batch. For eye irritation data, however, Reg. No. 6836-87 must cite its own data, and the other products may *not* cite that data.	1672-14	Pine oil 2.5% Alkyl* dimethyl benzyl ammonium chloride 0.76% *(50%C14, 40%C12, 10%C16) Didecyl dimethyl ammonium chloride 0.285% Octyl decyl dimethyl ammonium chloride 0.57% Dioctyl dimethyl ammonium chloride 0.285%
	6836-87	Pine oil 2.5% Alkyl* dimethyl benzyl ammonium chloride 0.76% *(50%C14, 40%C12, 10%C16) Didecyl dimethyl ammonium chloride 0.342% Octyl decyl dimethyl ammonium chloride 0.57% Dioctyl dimethyl ammonium chloride 0.228%
	10324-66	Pine oil 2.5% Alkyl* dimethyl benzyl ammonium chloride 0.76% *(50%C14, 40%C12, 10%C16) Didecyl dimethyl ammonium chloride 0.285% Octyl decyl dimethyl ammonium chloride 0.57% Dioctyl dimethyl ammonium chloride 0.285%
	24909-15	Pine oil 2.5% Alkyl* dimethyl benzyl ammonium chloride 0.76% *(50%C14, 40%C12, 10%C16) Didecyl dimethyl ammonium chloride 0.285%

Batch 8	EPA Reg. No.	% Active Ingredient
		Octyl decyl dimethyl ammonium chloride 0.57% Dioctyl dimethyl ammonium chloride 0.285%

Batch 9	EPA Reg. No.	% Active Ingredient
Each Batch 9 product must cite its own data or data from Reg. No. 5813-31.	5813-31	Pine oil 20% Didecyl dimethyl ammonium chloride 0.5625% Octyl decyl dimethyl ammonium chloride 1.125% Dioctyl dimethyl ammonium chloride 0.5625%
	5813-34	Pine oil 15% Didecyl dimethyl ammonium chloride 0.56% Octyl decyl dimethyl ammonium chloride 1.13% Dioctyl dimethyl ammonium chloride 0.56%

Batch 10	EPA Reg. No.	% Active Ingredient
Each Batch 10 product must cite its own data or data from any other product in the batch.	491-257	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	1190-48	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	2296-108	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	3862-112	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	4170-8	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	5449-10	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	6836-169	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)

Batch 10	EPA Reg. No.	% Active Ingredient
	8503-15	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	10324-124	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	10807-111	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	34282-13	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	37265-42	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	39272-11	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)
	45745-5	Pine oil 3.95% Alkyl* dimethyl benzyl ammonium chloride 1.97% *(58%C14, 28%C16, 14%C12)

No Batch	EPA Reg. No.	% Active Ingredient
Each "No Batch" product must cite its own data.	777-60	Pine oil 15% o-Phenylphenol 0.78%
	777-75	Pine oil 9% Alkyl* dimethyl benzyl ammonium chloride 0.8% *(50%C14, 40%C12, 10%C16) Didecyl dimethyl ammonium chloride 0.125% Octyl decyl dimethyl ammonium chloride 0.25% Dioctyl dimethyl ammonium chloride 0.125%
	1839-112	Pine oil 4% Alkyl* dimethyl benzyl ammonium chloride 1% *(60%C14, 30%C16, 5%C18, 5%C12) Alkyl* dimethyl ethylbenzyl ammonium chloride 1% *(68%C12, 32%C14)
	2230-57	Pine oil 5.08% Didecyl dimethyl ammonium chloride 2.08%
	2296-102	Pine oil 5% 2-Benzyl-4-chlorophenol 3.6%
	2296-105	Pine oil 15% 2-Benzyl-4-chlorophenol 2%
	3573-50	Pine oil 6%
	4313-41	Pine oil 6.4% Potassium 2-benzyl-4-chlorophenate 2.4%
	4482-13	Pine oil 3% Isopropyl alcohol 5% Alkyl* dimethyl benzyl ammonium chloride 3% *(50%C14, 40%C12, 10%C16)
	5741-16	Pine oil 1% Alkyl* dimethyl benzyl ammonium chloride 1.3% *(50%C14, 40%C12, 10%C16) Didecyl dimethyl ammonium chloride 0.45% Octyl decyl dimethyl ammonium chloride 0.9% Dioctyl dimethyl ammonium chloride 0.45%
	5813-30	Pine oil 20% Alkyl* dimethyl benzyl ammonium chloride 1.125% *(60%C14, 30%C16, 5%C18, 5%C12) Alkyl* dimethyl ethylbenzyl ammonium chloride 1.125%

No Batch	EPA Reg. No.	% Active Ingredient
		*(50%C12, 30%C14, 17%C16, 3%C18)
	5813-35	Pine oil 0.5% Didecyl dimethyl ammonium chloride 0.16% Octyl decyl dimethyl ammonium chloride 0.32% Dioctyl dimethyl ammonium chloride 0.16%
	5813-37	Pine oil 0.3% Alkyl* dimethyl benzyl ammonium chloride 0.2% *(50%C14, 40%C12, 10%C16)
	5813-56	Pine oil 6%
	6836-168	Pine oil 7.9% Alkyl* dimethyl benzyl ammonium chloride 3.95% *(58%C14, 28%C16, 14%C12)
	6836-177	Pine oil 23.81% Alkyl* dimethyl benzyl ammonium chloride 11.9% *(58%C14, 28%C16, 14%C12)
	8370-6	Pine oil 10% Alkyl* dimethyl benzyl ammonium chloride 1% *(50%C14, 40%C12, 10%C16)
	11715-290	Pine oil 40% Butoxypolypropylene glycol 50% Piperonyl butoxide 1% Pyrethrins 0.4%
	47371-102	Pine oil 2.48% Alkyl* dimethyl benzyl ammonium chloride 1.58% *(50%C14, 40%C12, 10%C16) Didecyl dimethyl ammonium chloride 2.37%
	47371-105	Pine oil 7.9% Alkyl* dimethyl benzyl ammonium chloride 3.95% *(50%C14, 40%C12, 10%C16)
	47371-153	Pine oil 3.94% Alkyl* dimethyl benzyl ammonium chloride 1.98% *(50%C14, 40%C12, 10%C16)
	49827-2	Pine oil 1.86%
	65595-1	Pine oil 19.9%
	72138-4	Pine oil 5%

No Batch	EPA Reg. No.	% Active Ingredient
	72138-6	Pine oil 5% Alkyl* dimethyl benzyl ammonium chloride 2.5% *(58%C14, 28%C16, 14%C12)

1. For products in Batches 2 through 5 with pH above 11.0, in lieu of conducting an eye irritation study, if the registrant decides to request a waiver based on possible corrosiveness, the study can be waived. Acute Toxicity Category I will then be assigned for eye irritation, and the signal word *DANGER* will be required on the product label. The following statements will also be required and must be placed in the *Hazards to Humans and Domestic Animals* section of the label: *DANGER. Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear [specify appropriate protective eyewear such as goggles, face shield, or safety glasses]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.*

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

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 that 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: http://npic.orst.edu .

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.