United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances

EPA 739-R-07-008
September 2007
(7510P)

Reregistration Eligibility Decision for 2-Octyl-3 (2H)-isothiazolone (OIT)

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 2-octyl-3 (2H)-isothiazolone (OIT) . The Reregistration Eligibility Decision (RED) for OIT was approved on September 28, 2007. 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 OIT 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 OIT are available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2007-0414 at: www.regulations.gov.

The OIT RED was developed through EPA's public participation process, published in the Federal Register on June 13, 2007, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. 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 OIT 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 OIT 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 OIT will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measure outlined in Section IV of the document. Sections IV and V of this RED document describe the labeling amendments for end-use products and data requirements necessary to implement this mitigation measure. 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 OIT. 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 relevant to this reregistration decision, please contact the Chemical Review Manager, K. Avivah Jakob, at (703) 305-1328. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Marshall Swindell at (703)-308-6341.

Sincerely,

Betty Shackleford for

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
2-Octyl-3 (2H)-isothiazolone (OIT)
List B
CASE 2475

Approved By:

Betty Shackleford for

Frank T. Sanders
Director, Antimicrobials Division
September 28, 2007

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
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	Protection factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
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

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for 2-Octyl-3 (2H)-isothiazolone (OIT) 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 OIT that pose risks of concern. As a result of this review, EPA has determined that OIT-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 initiated 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 revised human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for 2-Octyl-3 (2H)-isothiazolone (OIT).

OIT is currently registered as an industrial mildewcide, microbiocide, fungicide and bacteriocide. The primary use sites for octhilinone are as a material preservative (e.g., fabrics, textiles, coatings, sealants, adhesives, rubbers, plastics, leather preservation), as an industrial mildewcide for cooling tower and air washer water systems (e.g., air washer water, flow-thru cooling towers), and as a wood preservative (e.g., antisapstain drench).

The Agency has concluded that the FQPA Safety Factor for OIT should be removed (equivalent to 1X) based on: (1) the toxicology data base is complete with respect to assessing the increased susceptibility to infants and children as required by FQPA for OIT; (2) there is no concern for developmental neurotoxicity resulting from exposure to OIT in the rat and rabbit prenatal developmental studies and 2-generation reproduction study; (3) there is no evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies or to the offspring when adults are exposed in the two-generation reproductive study; and (4) the risk assessment does not underestimate the potential exposure for infants and children.

Risks summarized in this document are those that result only from the use of the active ingredient, OIT. 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 OIT and any other substances**.** OIT does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that OIT 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 OIT. 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 documents for OIT 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-2007-0414).

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 OIT and its regulatory history. Section III, Summary of OIT 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

OIT was first registered as an active ingredient by the United States Environmental Protection Agency (EPA) in 1971. OIT is currently registered as an industrial mildewcide, microbiocide, fungicide and bacteriocide. OIT is largely used as a material preservative, as an industrial mildewcide for cooling tower and air washer water systems and as a wood preservative. Currently there are 36 active product registrations containing OIT as an active ingredient.

B. Chemical Identification

Technical OIT

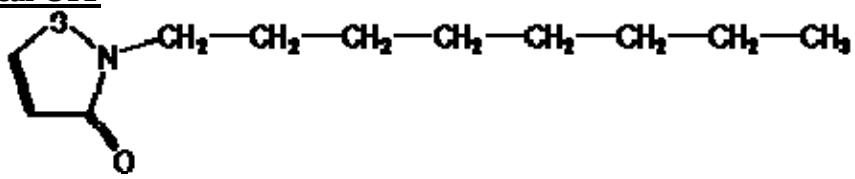

Figure 1. Molecular Structure of OIT

Common name: OIT or Octhilinone

Chemical name: 2-Octyl-3(2H)-isothiazolone

Chemical family: Thiazole, Ketone

Empirical formula: $C_{11}H_{99}ONS$

CAS Registry No.: 26530-20-1

Case number: 2475

OPP Chemical Code: 099901

Molecular weight: 213.34 g/mol

Other names: Kathon; RH-893; 2-n-Octyl-4-isothiazolin-3-one; 3(2H)-Isothiazolone, 2-octyl-; Microbicide M-8

Basic manufacturers: Rohm & Haas Co.; Lonza Inc.; Thor GMBH

Chemical properties: OIT is a yellow liquid with a mild odor and is stable when stored in ambient conditions. OIT has a specific gravity of 1.03; a water solubility of 0.525 g/L; a vapor pressure of 3.68 X 10^{-5} mm Hg @ 25 C ^{o}; and a viscosity of 48.04 mm^2/s at 20 EC and 17.94 mm^2/s at

40 ^{o}C. The log K_{ow} of OIT is 3.42 and its pH is 3.4. OIT has a half life of 3.3 hours in air.

C. Use Profile

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

Type of Pesticide: Mildewcide, Microbiocide, Fungicide and Bacteriocide

Summary of Use:

Materials Preservative:
As a materials preservative, OIT is used in industrial premises. There are no residential use sites for octhilinone as an active ingredient. However, octhilinone is used as a materials preservative in various end-use products, some of which can be handled and used in residential settings. Some examples of the types of treated materials that a residential user can come into contact with are paints, carpets, vinyl floors, mattresses, rubber/polymer products, and textiles (e.g. clothing and linens). Examples of materials that are treated with OIT include: fabrics and textiles (furniture, auto upholstery, footwear, carpet, carpet backing, tents, awnings, canvas, linens, wall and window coverings, dust towels, bedding, mattresses, pet bedding, pool liners, automotive trim, roof liners, marine upholstery, pond liners, synthetic brooms, mops, air filter media), coatings (walls, paints, plasters, stuccos), sealants (grouts, caulks, joint cements), adhesives (wallpaper pastes, gelatin and starch based), rubber and plastics (latex, acrylic, styrene, butadiene, polyvinyl chloride, polymethane, vinyl, foams), leather preservation (wet processes), metalworking fluid preservation and hydraulic fluid preservation.

Wood Preservative:
OIT is used to control sapstain and mold on wood via high pressure spray to logs that are processed to formulate plywood

Industrial Processes and Water Systems:
For use in industrial process and water systems including air washer water and once-thru cooling towers.

Target Pests: Deterioration/spoilage bacteria; fungi (coatings, leather, metal working coolants); mildew; mold; no pest; algae; animal pathogenic bacteria (g- and g+ vegetative); yeasts; ammonia-producing bacteria; dust mites; bacteria (unspecified); slime-forming fungi (paper mills/water systems); fungal rot/decay; bacteria (causing rot or decay); fungus growths; algae; barnacles; marine fouling organisms; tubeworms; sapstain.

Formulation Types: Formulation intermediate, soluble concentrate, ready to use, emulsifiable concentrate, pelleted tableted.

Methods and Rates of Application:

Equipment for Antimicrobial Use:

OIT end use products are added during the manufacturing process of treated articles and materials. Examples specific to materials preservation include: incorporation into the formulation of end use products; OIT is added at the beginning of the formulation process while mixing of the final product; OIT is incorporated with products during the manufacturing process; OIT is added to the final product prior to mixing; OIT is added to final rinse of fabric; OIT is incorporated into the tanning process; OIT is dispensed directly into metalworking concentrate; OIT is dispensed directly into the hydraulic concentrate using a metered pump for hydraulic fluid preservation. OIT is also applied via spray for wood preservation.

Application Rates: For details about specific use sites for OIT, refer to Appendix A.

- Concentrations of OIT in registered products (including both end use products and manufacturing use products) range from 1.29% to 99.4% OIT.
- The concentrations of OIT as an active ingredient in registered end-use products range from 1.29%-46.5%.

Use Classification: General use.

III. Summary of OIT 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 OIT. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2007-0414, and may also be accessed from 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.

The Agency's use of human studies in the OIT 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.

A. Human Health Risk Assessment

1. Toxicity of OIT

A brief overview of the toxicity studies used for determining endpoints in the risk assessment is outlined below in Table 1. Further details on the toxicity of OIT can be found in the "Evaluation of Toxicology Database for the Reregistration Eligibility Decision Document Disciplinary Chapter," dated August 13, 2007. This document is available on the Agency's website in the EPA Docket at: http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0414).

The Agency has reviewed all toxicity studies submitted for OIT 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.

Table #1. Summary of Acute Toxicity Data for OIT

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
Acute Toxicity				
870.1100	Acute oral toxicity	00070456	LD_{50} = 794 mg/kg (M) LD_{50}= 681 mg/kg (F)	III
870.1200	Acute dermal toxicity	00070456	LD_{50} = 1.83 gm/kg* (combined)	II
870.1300	Acute inhalation toxicity	00070456	LC_{50} >200 mg/kg	III
870.2400	Acute eye irritation	00070456	Severely Irritating	I
870.2500	Acute dermal irritation	00063214	Corrosive	I

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
870.2600	Skin sensitization	41482505, 41482507, 010809	Sensitizer	--

Notes: Octhilinone has a density of 1.03 gm/mL. = LD_{50} = 1.83 gm/kg

A dietary exposure assessment was not conducted for OIT and therefore, acute and chronic reference doses (RfDs) were not required. Based on the current labelled use patterns for OIT there are no dietary uses. Dietary exposure is not expected.

General Toxicity Observations

Acute Toxicity

OIT exhibits moderate oral, dermal, and inhalation toxicity (toxicity category III). For primary eye irritation, OIT is moderately irritating (toxicity category III). OIT is corrosive to the skin and is a dermal sensitizer. OIT is not mutagenic in activated and non-activated conditions and there is no evidence of a geno-toxic effect.

Acute and Chronic Reference Dose (RfDs)

Dietary exposure to OIT is not expected. Therefore, acute and chronic dietary endpoints were selected.

Incidental Oral Exposure

For the short-term (< 30 days) and intermediate-term (30 days – 6 months) incidental oral exposures, a NOAEL of 5 mg/kg/day was selected. The NOAEL was based on systemic effects in maternal rats (mortality, decreased body weight gain, decreased food consumption) observed at 30 mg/kg/day in a developmental rat toxicity study (MRID 41482508). The target margin of exposure (MOE) is 100 for short-term (ST) durations and 300 for intermediate-term (IT) durations.

Dermal Exposure

For short-term (ST) dermal exposures, a NOAEL of 10 mg/kg/day (equivalent to 0.0674 mg/cm^2) was selected from a 14 day dermal toxicity study in rats (MRID 43935705) based on dermal irritation in both sexes of rats. The target MOE is 10 for the ST dermal duration. While a MOE of 100 is usually applied, an MOE of 10 is used for this assessment for the following reasons (3x inter-species variation, 3x intra-species variation). The known short-term duration of dermal irritation and the use of a semi-occlusive dressing in the study support reducing the standard MOE. For intermediate-term (IT) dermal exposures, a NOAEL of 5.95 mg/kg/day was selected from a 90-day dermal toxicity study in rats (MRID 42007301) based on systemic effects (decreases in HGB, GCT, RBC, albumin, and total protein and a decrease in body weight gain in

male rats). The target MOE for IT dermal exposure is 100. There are no long-term dermal endpoints selected for OIT.

Inhalation Exposure

For short- and intermediate-term inhalation exposures, a NOAEL of 0.64 mg/m^3 was selected (equivalent to 0.18 mg/kg/day) from a 90-day inhalation study in rats (MRID 41544701). Effects observed at the LOAEL of 6.39 mg/m^3 (NOAEL is 0.64 mg/m^3) included clinical signs (rales, dyspnea) decreases in body weight gain, fluid in uterus and pulmonary and nasal cavity pathology. For the OIT risk assessment, human equivalent concentrations (HECs) were calculated using the regional deposited dose ratio (RDDR) for nonhygroscopic particles and the study NOAEL of 0.64 mg/m^3. These values are: 2 hr HEC: 0.29 mg/m^3, 4 hr HEC: 0.15 mg/m^3, 6 hr HEC: 0.10 mg/m^3 and 8 hr HEC: 0.073 mg/m^3. The target MOE for inhalation exposures is 30. An uncertainty factor of 30 is employed (3x for interspecies extrapolation, 10x for human variability). A 3x for interspecies extrapolation is used in place of the standard 10x factor as calculation of the RGDR (Regional Gas Dose Ratio) incorporates dosimetric adjustments and, therefore, accounts for pharmacokinetic differences between animals and humans, leaving the 3x pharmacodynamic uncertainty component.

Carcinogenicity

The available carcinogenicity data (TRID 4701030204/ MRIDs 00139417, 00139419, 00139484) are unacceptable and do not satisfy the guideline requirements for a carcinogenicity study in rodents. The metal working fluid use of OIT triggers the need for carcinogenicity data in the rat and mouse.

Mutagenicity Potential

OIT was found to be negative in the reverse mutation assay with Ames Salmonella (MRID 43935708), in a mouse bone marrow chromosomal aberration test (MRID 43935710), and in a mammalian cell in culture gene mutation assay (MRID 43935709). OIT is not mutagenic in activated and non-activated conditions and there is no evidence of genotoxic effect. Therefore, OIT is not mutagenic or genotoxic.

Endocrine Disruption Potential

The 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), the 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. The EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, the 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, OIT 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. OIT is not used in food and therefore, the toxicological database is considered to be complete with respect to assessing the increased susceptibility to infants and children as required by FQPA. There are no food tolerances for OIT and the use patterns considered for the reregistration eligibility decision (RED) document do not involve dietary exposure. As a result, an FQPA safety finding is not applicable.

3. Dietary Exposure Assumptions & Dietary Risk Assessment

A dietary risk assessment was not conducted for OIT and therefore, acute and chronic reference doses (RfDs) were not required. Based on the current use patterns for OIT, there are no dietary uses. However, there are several product labels that incorporate OIT as a materials preservative in adhesives during the manufacturing processes. These products are restricted from food contact.

The Agency addressed the possibility of indirect food contact resulting from adhesives preserved with OIT. It was determined that dietary exposure resulting from possible indirect food contact is not expected and a complete dietary assessment was not needed. All labels with the adhesive use pattern contain language that either specify the type of adhesive (e.g., wallpaper adhesive); or, the labels state that the products are for non-food use contact. Therefore, it is unlikely that treated adhesives will end up in food packaging materials.

a. Dietary Risk from Drinking Water

A drinking water assessment was not conducted for OIT because there are no registered outdoor uses for OIT, with the exception of the antisapstain wood preservative use. A dietary risk assessment was not conducted for the once-through cooling tower use because the registrant has indicated that they will voluntarily cancel this use. In order to be eligible for reregistration, this use must be removed from all product labels. Therefore, OIT it is not expected to contact fresh water environments. Octhilinone is stable and persistent in water under abiotic conditions, but shows a tendency to biodegrade in biotic environments. Also, a soil migration study supports that OIT is not expected to be prominent or migrate into water runoff since it binds strongly to the surfaces of soils. OIT does have a tendency to remain on the surface of soils.

However, the potential for contamination of surface water, as a result of rainfall, is unlikely to occur because of OIT's tendency to biodegrade in soils and its minimal outdoor uses.

The Agency acknowledges that there is a very small chance that the antisapstain use of OIT, could potentially result in leaching and runoff when freshly treated wood is stored outdoors. This risk can potentially be mitigated with precautionary antisapstain label language. For further information regarding the drinking water assessment please refer to the "Revised Octhilinone Risk Assessment for the Reregistration Eligibility Decision (RED) Document," dated September 20, 2007; the "Environmental Fate Assessment of Octhilinone," dated March 30, 2007; and the "Transmittal of Octhilinone (OIT) RED Ecological Hazard and Environmental Risk Assessment Chapter-Case Number 2475," dated March 7, 2007.

4. Residential Risk Assessment

There are no residential use sites for OIT as an active ingredient. However, OIT is used as a materials preservative in various end-use products, some of which can be handled and used in residential settings. Residential exposure to OIT can occur from contact with end-use products treated with OIT. Some examples of the types of treated materials that a residential user can come into contact with are paints, carpet, vinyl floors, mattresses, rubber/polymer products, and textiles (e.g., clothing and linens).

The residential exposure assessment considered all potential pesticide exposure, other than exposure due to residues in food and drinking water. Each route of exposure (oral, dermal, inhalation) was assessed, where appropriate, and risk was expressed as a Margin of Exposure (MOE). The MOE is the ratio of estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose.

a. Residential Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, residential and occupational risks for OIT are listed in Table 6.

The target Margin of Exposure (MOE) varies by route and duration of exposure. For OIT, the target MOE for incidental oral exposure is 100 for short-term (ST) and 300 for intermediate-term (IT) durations. For dermal exposures leading to irritation, the target MOE is 10 for ST and 100 for IT duration. For inhalation exposures, the target MOE is 30 for both short- and intermediate-term exposure durations.

Table #2. Residential and Occupational Toxicological Doses and Endpoints for OIT

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOEs for Risk Assessment	Study and Toxicological Effects
Incidental Oral, Short-Term; Intermediate-Term (1-30 days; 30 days-6 months)	Systemic NOAEL= 5 mg/kg/day	MOE= 100 (ST) (10x inter-species variation; 10x intra-species variation) MOE= 300 (IT) (10x inter- species variation; 10x intra-species variation; 3x for extrapolation to intermediate-term from short-term endpoint)	Developmental toxicity study (MRID 41482508) Systemic: Mortality, decreased body weight and body weight gain, decreased food consumption.
Dermal Exposure, Short-Term (1-30 days) [5 x 7 cm application area]	Dermal Irritation NOAEL= 10 mg/kg/day (0.0674 mg/cm$^{2)}$	Dermal Irritation MOE= 10 (ST)[a] (3x inter-species variation; 3x intra-species variation)	14 Day Dermal Study (MRID 43935705) Dermal: Dermal irritation in both sexes. Systemic: No systemic effects.
Dermal Exposure, Intermediate-Term (30 days - 6 months) [4 x 5 cm application area]	Systemic NOAEL= 5.95 mg/kg/day	MOE= 100 (IT) (10x inter-species variation; 10x intra-species variation)	90 Day Dermal Study (MRID 42007301) Systemic: Decreases in HGB, HCT, RBC, albumin, and total protein. Decrease in body weight gain in the male.
Dermal Exposure, Long-Term (>6 months)	Not Selected	Not Selected	Not Selected
Inhalation Short-Term; Intermediate-Term (0-30 days)/ (30 days to 6 months)	2 hr HEC: 0.29 mg/m^3 4 hr HEC: 0.15 mg/m^3 6 hr HEC: 0.10 mg/m^3 8 hr HEC: 0.073 mg/m^3 MOE = 30[b]	MOE= 30 (ST/IT)	90 Day Inhalation Toxicity (MRID 41544701) Clinical signs (rales, dyspnea) decreases in body weight gain, fluid in uterus and pulmonary and nasal cavity pathology.

a The use of dermal irritation is applied only for the short-term dermal exposure scenario. A margin of exposure (MOE) of 10 is used for the short-term assessment (3x inter-species variation, 3x intra-species variation).

b Human Equivalent Concentrations (HECs) were calculated using the Regional Deposited Dose Ratio (RDDR) for nonhygroscopic particles and the study NOAEL of 0.64 mg/m^3 Where, HEC = RDDR x NOAEL x (6hr (rats exposure time in study) / hr (worker exposure time))

Notes: UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, LOC = level of concern, MOE = margin of exposure

b. Residential Handlers

i. Exposure Assessment

Based on examination of product labels describing uses for OIT, it has been determined that exposure to handlers can occur in a variety of residential environments. Although no products containing OIT are labeled for residential use, residents may be exposed to household items that have been treated with OIT through material preservation (e.g., carpet, paints, and plastics). For the residential exposure risk assessment the EPA selected high-end exposure scenarios that are considered to be representative of all OIT residential handler exposure scenarios. The representative scenarios selected by the Agency were evaluated using maximum application rates as stated on the product labels. To assess the handler and post-application exposures and risks, the Agency used standard assumptions, surrogate unit exposure data (from the Chemical Manufacturers Association (CMA) antimicrobial exposure study, the Pesticide Handlers Exposure Database (PHED), 2005 *Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products* (HERA), and EPA's Health Effects Division's (HED) *Standard Operating Procedures (SOPs) for Residential Exposure Assessments).* Table 3 identifies the representative exposure scenarios assessed.

Table #3. Representative Uses Associated with Residential Exposure

Representative Use	Exposure Scenario	Application Method	Registration #	Application Rate
Using treated paints	ST handler: dermal (irritation) and inhalation (aerosol)	• brush/ roller • airless sprayer	67071-31	0.23% a.i. by weight (16.84% a.i. x 13.8 lb product/1000 lb paint)
Using treated carpet	ST and IT post-app: child incidental ingestion and dermal	NA	67071-6	0.12% a.i. by weight (0.25% product by weight of material x 46.5% a.i. in product)
Using treated vinyl floor	ST and IT post-app: child incidental ingestion and dermal	NA	67071-43	0.37% a.i. by weight (4% product by weight of material x 9.3% a.i. in product)
Using treated textiles (e.g., clothing and linen)[a]	ST post-app: child incidental ingestion and dermal	NA	67071-6	0.12% a.i. by weight (0.25% product by weight of material x 46.5% a.i. in product)
Using treated mattress covers	ST and IT post-app: child dermal	NA	81348-8	0.4% a.i. by weight (2% product by weight of material x 20% a.i. in product)
Using treated plastic/polymer	ST post-app: infant/child	NA	81348-8	0.4% a.i. by weight (2% product by weight of material x 20% a.i. in

Representative Use	Exposure Scenario	Application Method	Registration #	Application Rate
products	incidental ingestion			product)

[a] Exposure to OIT as a preservative for fabrics/textiles is assumed to also represent exposure to leather processed using OIT preserved products.

Short-term inhalation and dermal residential painter exposures were assessed and are considered to be representative of all other residential handler exposures. Only short-term exposure durations (1 to 30 days) were estimated because it was assumed that a homeowner or do-it-yourself painter would typically paint on an intermittent basis (i.e., once or twice a year).

Inhalation Exposure

Residential handlers using preserved treated paint may have inhalation exposures to both aerosols and vapors. In the case of OIT, the vapor pressure is relatively low therefore the vapor phase did not required evaluation. Only inhalation exposure to paint aerosols was quantitatively assessed.

There are no chemical-specific exposure data to assess paint application via paint brush, roller, or airless sprayer. Therefore, inhalation exposure was assessed for these scenarios using surrogate data. The surrogate data are based on the Pesticide Handler Exposure Database (PHED) and National Paints and Coatings Associate (NCPA) data for painters wearing no respiratory protection.

For the brush/roller scenario**,** the PHED inhalation unit exposure value for a residential handler applying a pesticide using a paint brush was used. The test subjects were painting a bathroom with a paint brush. This unit exposure value (0.28 mg/lb a.i.) represents a handler wearing no respiratory protection.

For the airless sprayer scenario, the PHED inhalation unit exposure value for a residential handler applying a pesticide using an airless sprayer was used. The test subjects were staining the outside of a house with an airless sprayer. Although these exposures may differ slightly from exposures of painters to OIT persevered products, these data are judged to be adequately representative. The inhalation unit exposure value for the airless sprayer application was available in terms of an air concentration (mg/m^3/% a.i.) as well as, in terms of amount handled (mg/lb a.i.). Since the inhalation toxicity endpoint was determined from an inhalation study (as opposed to an oral study), the endpoint units are given in terms of an air concentration (mg/m^3). Therefore, in order to estimate inhalation risks (MOEs), it was appropriate to use the unit exposure value in terms of an air concentration (mg/m^3/% a.i.) rather than amount handled (mg/lb a.i.). The inhalation unit exposure value of 0.68 mg/m^3/% a.i was used for baseline (i.e., no respirator) exposures.

For the airless sprayer scenario, the OIT Task Force provided an additional exposure study to supplement the existing PHED data. The purpose of this study, conducted by the

National Paints and Coatings Association (NPCA) (Reinhardt and Fendick, 2000), was to estimate exposure to crystalline silica while spray painting or sanding three different formulations of latex paint in an indoor environment. Although the study was conducted to specifically evaluate crystalline silica exposure, respirable aerosol *paint* concentrations were measured during airless spraying activities. Each of the three paint formulations was applied by a professional painter on three consecutive days resulting in nine samples of respirable aerosol paint concentrations. The test worker painted the walls and ceilings of rooms measuring 8 feet high, 10 feet wide, and 12 feet long. A daily painting exposure test (i.e., 8 hour work day) required painting five to eight standard rooms while each room took 17 – 34 minutes to complete. The results showed that the average respirable aerosol breathing zone concentration during airless spraying of paint was 3.67 mg/m^3. The NPCA study suggests that the respirable aerosol mass in the breathing zone was no more than 16% of the total mass measured. Therefore, because the endpoint was based on nasal irritation, the respirable aerosol paint concentration of 3.67 mg/m^3 was adjusted up by 16% to estimate the inhalable aerosol paint concentration (i.e., air concentration up to 100 microns) of 22.91 mg/m^3. These data were used to further characterize the airless sprayer inhalation exposure even though the following were identified as uncertainties or limitations in the NCPA study:

- The study did not provide raw data to support the statement that the respirable aerosol mass in the breathing zone was no more than 16% of the total mass measured;
- The particle sizes were not actually measured;
- No cut point was provided for the size of respirable or inhalable aerosols

Based on these limitations, an additional study is needed to determine aerosol size distribution that is less than 100 microns. Furthermore, there is insufficient information on the distribution on the aerosol size/diameter from the PHED data using the 2L/min sampling pump with sampling cassettes facing downwards to adjust total aerosols to inhalable particle size (i.e., 100 microns). Without this data, the air concentrations estimates using the PHED data can not be adjusted down to estimate only inhalable for the aerosol size distribution, as suggested by the OIT Task Force.

The inhalation unit exposure value for the brush/roller technique is reported as unit exposures (UE), which is expressed as mg/lb of active ingredient handled. The inhalation unit exposure for the airless sprayer technique was provided in terms of an air concentration (mg/m^3/% a.i.) as well as in terms of amount handled (mg/lb a.i.). Since the inhalation toxicity endpoint was determined from an inhalation study (as opposed to an oral study), the endpoint units are given in terms of an air concentration (mg/m^3). Therefore, in order to more accurately estimate inhalation risks (MOEs), it was appropriate to use the unit exposure value in terms of an air concentration (mg/m^3/% a.i.) rather than amount handled (mg/lb a.i.) for the airless sprayer application method. The inhalation unit exposure value of 0.68 mg/m^3/% a.i was used for baseline (i.e., no respirator) exposures.

To assess residential handler exposure, the quantities handled/treated were estimated based on information from various sources and assumptions (e.g., maximum application rates, related use information, etc.) For the brush/roller in-can paint applications, it was assumed that 20 lbs (approximately 2 gallons) of treated paint will be used. This is based on the 90th percentile value of 8 gallons of latex paint used per year divided by the mean frequency of 4 painting events/year. It was assumed that it could take residential applicators 2, 4, or 6 hours to apply paint using a brush/roller or airless sprayer.

Dermal Exposure

To estimate the potential for dermal irritation, a dermal exposure based on surface area was calculated. Because the short-term (ST) dermal toxicological endpoint is based on skin irritation and not systemic effects; and because the endpoint is provided in terms of body surface area, the exposure was calculated in terms of body surface area (i.e., mg a.i. per cm^2 exposed skin surface area). Dermal irritation is a relevant toxicological endpoint for ST dermal exposures.

The percent active ingredient was calculated using information from the product label that results in the maximum exposure to OIT (EPA Reg. No. 67071-31, with 16.84% a.i.). For short-term dermal irritation effects, the film thickness of the paint on the hands was assumed to be 10.3 mg/cm^2. This film thickness value is based on a measurement where a worker completely immersed both hands into mineral oil and allowed no wiping (US EPA 1992). Using this film thickness may result in an underestimate of exposure because the actual film thickness of paint is potentially higher than the film thickness of mineral oil. A more accurate assessment would require a dermal irritation study using paint as the test substance.

The "paint matrix effect" parameter pertains to the observation that OIT is essentially "bound" within the paint matrix thereby reducing the potential dermal exposure. The OIT Task Force submitted a study that evaluated the amount of OIT that was available on the skin for exposure when used in a paint matrix (DiDonato and Hazelton, 1990). The percentages of radio-labeled OIT formulated in solvent systems (ethanol and acetone) and paints (a water-based paint and a solvent-based stain) remaining on guinea pig skin were compared after 3 hours of exposure. The 3 hour duration was selected as the worst case to ensure that the paint would be wet (a dry film would further bind the OIT to the paint).

By taking into account the ratios of the amount of OIT from paint to the amount of OIT from the solvent (i.e., 4/36 to 8/29), it appears that OIT is available for dermal exposure in the range of 11% – 28% when formulated in the paint matrix as compared to a solvent. Based on these results, 28% was used for the paint matrix effect parameter.

ii. Risk Assessment

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments. A MOE greater than or equal to 30 is considered

adequately protective for the residential inhalation exposure assessment. A MOE greater than or equal to 10 is considered adequately protective for the residential dermal exposure assessment.

For the residential handler inhalation exposure assessment, the short-term inhalation MOEs estimated for use of a brush/roller are above the target MOE of 30 and, therefore, are not of concern. However, the short-term inhalation MOEs estimated for the airless sprayer use scenarios are below the target MOE of 30. Therefore, there are inhalation risks of concern for the application of paint via airless sprayer. A summary of the inhalation exposures and risks for residential painters can be found in tables 4 & 5.

Table #4. Short-term Inhalation Exposure and MOE for Residential Painter Using a Brush or Roller

Method of Application	Inhalation Unit Exposure (mg/lb a.i.)	App. Rate (% ai)	Quantity Handled (lb/day)	Daily Dose (mg/kg/day) [a]	Air Conc. (mg/m^3) [b]	HEC (mg/m^3)	MOE (ST) [c]
Brush/roller	0.28	0.23%	20 lbs (2 gal)	0.00018	0.0016	0.29 at 2 hrs	180
	0.28	0.23%	20 lbs (2 gal)	0.00018	0.0016	0.15 at 4 hrs	90
	0.28	0.23%	20 lbs (2 gal)	0.00018	0.0016	0.10 at 6 hrs	60

a Inhalation Daily Dose (mg/kg/day) = inhalation unit exposure (mg/lb a.i.) x application rate x quantity handled / body weight (70 kg).

b Air conc.(mg/m^3) = Dose (mg/kg/day) x BW (70 kg) x Light activity inhalation rate ($day/8m^3$)

c Inhalation MOE = HEC (mg/m^3) / Air conc. (mg/m^3). Target inhalation MOE is 30.

Table #5. Short-term Inhalation Exposures and MOEs for Residential Painter Using an Airless Sprayer

Method of Application	App.Rate (% a.i.)	Inhalation Unit Exposure PHED (mg/m^3/%ai) NPCA (mg/m^3)	Air Conc. (mg/m^3)[a]	HEC (mg/m^3)	Route Specific MOE (ST) [b]
Airless Sprayer (PHED)	0.23%	0.681	0.16	0.29 at 2 hrs	**2**
	0.23%	0.681	0.16	0.15 at 4 hrs	**1**
	0.23%	0.681	0.16	0.10 at 6 hrs	**1**
Airless Sprayer (NPCA)	0.23%	22.91	0.0053	0.29 at 2 hrs	**6**
	0.23%	22.91	0.0053	0.15 at 4 hrs	**3**
	0.23%	22.91	0.0053	0.10 at 6 hrs	**2**

[a] Air conc (mg/m^3) = App Rate (%ai) x PHED UE (mg/m^3/%ai)
(Note that the %ai incorporated the PHED UE is in terms of whole numbers, not fraction (i.e., 0.23 not 0.0023), therefore the App rate is used as a whole number in the Air conc. estimate)
Air conc (mg/m^3) = App Rate (%ai) x NPCA UE (mg/m^3)
(Note that the App rate is used as a weight fraction in the Air conc. estimate (i.e., 0.0023)
[b] Inhalation MOE = HEC (mg/m^3) / Air conc. (mg/m^3). Target inhalation MOE is 30.

For the residential handler dermal exposure assessment, the short-term dermal MOE for a painter applying treated paint is 10. There are no residential dermal risks of concern because the calculated MOE of 10 is not below the target MOE of 10. A summary of the residential handler dermal exposures and risks is presented in Table 10 below.

Table #6. Short-term Dermal Exposures & MOEs for Residential Painter

Exposure Scenario	% ai	Film thickness (mg/cm^2)	Paint Matrix Effect (%)	Exposure (mg/cm^2)	Dermal MOE (Target MOE is 10) [a]
Painter	0.23%	10.3	28%	0.0067	10

a MOE = NOAEL (mg/cm^2) / Potential exposure (mg/cm^2) [Where: NOAEL for short-term dermal irritation = 0.0674 mg/cm^2, Table 3.2].

c. Residential Post-application

i. Exposure Assessment

Post-application scenarios have been selected that encompass multiple products. These selected scenarios represent high-end exposures and include: contacting treated carpets and vinyl floors (dermal and incidental oral exposure to children), wearing treated clothing (dermal exposure to children and adults), using treated mattresses (dermal exposure to children and adults), mouthing treated textiles such as clothing and blankets (incidental oral exposure to children), and mouthing treated plastic toys (incidental oral exposure to children). It should be noted that because OIT has a relatively low vapor pressure, post-application inhalation exposures were not assessed.

Data sources and methodologies utilized for both the handler and post-application residential risk assessment include: the HED Residential Standard Operating Procedures (SOPs) (USEPA, 1997a), the USEPA Exposure Factors Handbook (USEPA 1997b), Recommended Revisions to the Residential SOPs (USEPA, 2001), and the Human and Environmental Risk Assessment (HERA) Guidance Document (2003).

The Agency evaluated the following post-application scenarios, which are considered to be representative of all possible post-application residential exposure scenarios:

- Contact with treated carpets by children (ST & IT incidental oral and dermal exposure to children);
- Contact with treated vinyl by children (ST & IT incidental oral and dermal exposure to children);
- Treated mattress covers (ST & IT dermal exposure to children and adults);
- Treated clothing/textiles (ST dermal exposure to children & adults, ST incidental oral exposures to children);
- Mouthing treated plastic toys (ST incidental oral exposure to children).

There is potential for exposure to occur for greater than 30 days, assuming that OIT has a relatively long half life indoors, from treated carpet, treated vinyl, and treated mattress covers. Therefore, both short- and intermediate-term exposure durations were assessed for the treated carpet, vinyl, and mattress cover scenarios. A long-term residential exposure assessment was not conducted for OIT. Typically the Agency does not conduct long-term residential exposure assessments, other than for dietary and drinking water exposures, because residential use of treated materials is expected to be intermittent. Even with a relatively high half-life, the Agency does not expect long-term exposure of residents to treated materials. Therefore, a long-term post-application residential exposure assessment was not conducted for OIT.

For treated textiles, it was assumed that not all clothing is treated with OIT and the clothing that is treated will not be worn everyday. Therefore, exposure would occur intermittently. It was also assumed that not all plastic toys are treated with OIT and the toys that are treated will not be used everyday, resulting in intermittent exposure. Therefore, only short-term exposure durations were assessed for treated textiles and toys (plastics).

ii. Risk Assessment

Based on toxicological criteria and potential for exposure, the Agency has conducted residential handler post-application dermal and incidental oral exposure assessments. The residential post-application risk assessment identifies short-term (1-30 days) and intermediate-term (1-6 months) exposure doses. A MOE greater than or equal to 10 is considered adequately protective for short-term (ST) dermal exposure to OIT; and an MOE of 100 is considered adequately protective for intermediate-term (IT) dermal exposures. For incidental oral exposure, a MOE greater then or equal to 300 is considered adequately protective for intermediate-term (IT) durations; and a MOE of 100 is considered adequately protective for ST incidental oral durations. A MOE greater then or equal to 30 is considered to be adequately protective for ST/IT inhalation exposure.

For the residential post-application risk assessment, MOEs are above the respective target MOEs (10 for ST dermal exposures, 100 for IT dermal exposures, 30 for ST/IT inhalation exposures, 100 for ST incidental ingestion exposures, and 300 for IT incidental ingestion exposures) for all scenarios except for the following. The following residential post-application exposure scenarios are of concern:

- ST dermal exposure of children to treated carpet: $MOE_{5\% \text{ transfer}} = 9$
- IT dermal exposure of children to treated carpet: $MOE_{5\% \text{ transfer}} = 6$
- ST incidental ingestion exposure of children to treated carpet: $MOE_{5\% \text{ transfer}} = 6$
- IT incidental ingestion exposure of children to treated carpet: $MOE_{5\% \text{ transfer}} = 13$
- IT dermal exposure of children to treated mattresses: $MOE_{5\% \text{ transfer}} = 73$ ($MOE_{100\% \text{ transfer}} = 4$)
- ST dermal exposure of adults and children to treated mattresses: $MOE_{5\% \text{ transfer}} = 67$ ($MOE_{100\% \text{ transfer}} = 3$)

The following residential post-application exposure scenarios are of concern at a 100% transfer factor; however, they are not of concern with a 5% transfer factor. Therefore, confirmatory data are required to verify the 5% transfer factor.

- ST dermal exposure of adults & children to treated clothing: $MOE_{100\% \text{ transfer}} = 6$; $MOE_{5\% \text{ transfer}} = 116$
- IT dermal exposure of adults to treated mattresses: $MOE_{100\% \text{ transfer}} = 5$; $MOE_{5\% \text{ transfer}} = 110$

Table 7 presents a summary of the short-term and intermediate-term residential post-application exposures and risk estimates.

Table #7. Short- and Intermediate-term Residential Post-application Risks for Adults & Children

Exposure Scenario	Dermal MOE Target MOE 10 (ST) Target MOE 100 (IT)	Incidental Ingestion MOE Target MOE 100 (ST) Target MOE 300 (IT)
Child contacting treated carpet (ST)	9 @ 5% transfer	6 @ 5% transfer
Child contacting treated carpet (IT)	6 @ 5% transfer	13 @ 5% transfer
Child contacting treated vinyl (ST)	5,200 @ 10% transfer	7,200 @ 10% transfer
Child contacting treated vinyl (IT)	6,300 @ 10% transfer	15,000 @ 10% transfer
Treated Clothing for Children and Adults (ST)	6 @ 100% transfer 116 @ 5% transfer	130 (for children) NA (for adults)
Treated Mattress Covers – Children & Adults (ST)	3 @ 100% transfer 67 @ 5% transfer	NA
Treated Mattress Covers – Children (IT)	4 @ 100% transfer 73 @ 5% transfer	NA
Treated Mattress Covers – Adults (IT)	5 @ 100% transfer 110 @ 5% transfer	NA
Treated Plastics (ST) – Children mouthing toys	NA	152

NA= Not applicable

8. Aggregate Risk Assessment

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 typically includes exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

The aggregate risk assessment is designed to provide estimates of risks likely to result from exposures to the pesticide or pesticide residues in food, water, and from residential (or other non-occupational) pesticide uses. Acute and chronic dietary aggregate assessments were not conducted because there are no uses for OIT attributable to these routes of exposures. Inhalation exposures were not considered in the aggregate risk assessment because there are no inhalation post-application scenarios to be considered. To reiterate, OIT has a low vapor pressure and, therefore, any potential exposures to OIT vapors were not necessary to assess.

Since the endpoint for each route of exposure was based on a route specific study resulting in different effects, separate route specific aggregate assessments were conducted. The use patterns of the products and probability of co-occurrence were taken into account when selecting use scenarios for the aggregate assessment. Because most of the OIT products are used as a materials preservative in the manufacturing of various materials and exposure to some of these materials (e.g., mattresses, carpets, vinyl tiles) can occur on a continuous basis, they were included in the aggregate assessments. It should be noted that based on the probability of co-occurrence of the uses that have intermediate-term exposure potential, it was determined that an adult intermediate-term aggregate assessment was not necessary to conduct.

Table 8 summarizes the use scenarios that were assessed for the short-term (non-dietary, non-occupational) aggregate assessment.

Table #8. Short-term Aggregate Exposure Use Scenarios

ST Aggregate Exposure Scenarios	
Adults	**Dermal:** • exposure to residues in **fabrics/clothing** preserved during manufacturing • exposure to residues in **mattresses** preserved during manufacturing
Children	**Dermal:** • exposure to residues in **fabrics/clothing** preserved during manufacturing • exposure to residues in **mattresses** preserved during manufacturing • exposure to residues in **vinyl tiles** preserved during manufacturing
	Oral: • exposure to residues in **fabrics/clothing** preserved during manufacturing • exposure to residues in **polymers (toys)** preserved during manufacturing • exposure to residues in **vinyl tiles** preserved during manufacturing

Quantitative assessments were not conducted for use scenarios that have individual risks of concerns, such as dermal exposures to treated carpets. Dermal post-application exposures to OIT carpet residues, alone, are of concern to the Agency. An aggregate assessment would only reflect the previously identified individual risks of concern and incorporation of this scenario in the aggregate assessment would result in risks of concern. Therefore, the carpet scenario was not incorporated in the aggregate assessment. If these exposures did not result in individual risks of concern, then they would have been included in the aggregate assessments instead of exposures to vinyl floors.

a. Short-Term Aggregate Risk

The endpoint for each route of exposure was based on a route specific study resulting in different effects and therefore, separate route specific aggregate assessments were conducted. The total MOE method outlined in the OPP guidance for aggregate risk assessment (September 1, 2000, *Standard Operating Procedure (SOP) for Incorporating Screening Level Estimates of Drinking Water Exposure into Aggregate Risk Assessments*) was utilized. This method was used because the oral, dermal and inhalation endpoints have the same uncertainty factors or target MOEs. The target MOE for all ST dermal exposure is 10 and ST oral is 100.

Tables 9 and 10 present the MOEs for the short-term dermal and short-term oral aggregate assessments. The short-term dermal aggregate MOEs for adults and children were above the target MOE of 10 and, therefore, are not of concern. However, the short-term oral aggregate MOE for children was below the target MOE of 100 and, therefore, indicates a risk of concern.

Table #9. Short-term Dermal Aggregate Assessments

	MOEs				
Exposure Route	**Vinyl**	**Clothing**	**Mattress**	**Aggregate**	**Target MOE**
Adults Dermal	NA	116	67	42	10
Children Dermal	5,200	116	67	42	10

a: Aggregate MOE = 1/((1/MOEvinyl) + (1/MOEclothing) + (1/MOEmattress))

Table #10. Short-term Oral Aggregate Assessments

	MOEs				
Exposure Route	**Vinyl**	**Clothing**	**Toys**	**Aggregate**	**Target MOE**
Children Incidental Oral	7,200	130	150	**69**	100

a: Aggregate MOE = 1/((1/MOEvinyl) + (1/MOEclothing) + (1/MOEtoys))

9. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. OIT is used as a materials preservative, as an industrial mildewcide for cooling tower and air washer water systems, and as a wood preservative. Potential occupational handler exposures can occur during the preservation of materials that are used for institutional and industrial uses. The “preservation of materials” refers to the scenario of a worker adding the preservative to the material being treated (metalworking fluid, paint, textiles, etc.) through either liquid pour or liquid pump methods. In addition, there is the potential for occupational handlers to come into contact with treated products such as metalworking fluids, paints, treated wood, etc.

Occupational handlers of OIT include handlers applying OIT treated paint via airless sprayer or paint brush/roller; handlers pouring OIT liquid preservative for the preservation of paints, plastics, vinyl, leather, textiles, and metal working fluids; handlers pumping OIT liquid preservative for preservation of metalworking fluids, paints, plastics, vinyl, leather (metering

pump), textiles, and mattresses (mechanical metering pump); and wood preservative application via high pressure spray.

An exposure assessment was not conducted for the industrial processes and water systems use (water system biocide use). The water system uses are only listed on one manufacturing use product (MUP) label (Reg. #707-308), which does not provide application or use rates. Since there are no end-use product (EUP) labels containing water system uses, these uses were not assessed. The water systems use should be canceled and manufacturing use product labels need to be updated. If this use is not cancelled, new end-use product labels need to be formally submitted and reviewed by the Agency.

a. Occupational Toxicity

The toxicological endpoints used in the occupational handler assessment of OIT can be found in Table 6, "Residential and Occupational Toxicological Doses and Endpoints for OIT", of this document.

b. Occupational Handler Exposure

Occupational risk for all potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. 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.

Potential occupational handler exposures can occur during the preservation of materials that are used for institutional and industrial uses, along with the use of cooling water tower biocides and wood preservatives. The "preservation of materials" refers to the scenario of a worker adding the preservative to the material being treated (metalworking fluid, paint, textiles, leather, etc.) through either liquid pour or liquid pump methods. Liquid pour refers to transferring the antimicrobial product from a small container to an open vat. Liquid pump refers to transferring the preservative by connecting/disconnecting a chemical metering pump from a tote or by gravity flow.

The Agency evaluated representative occupational handler scenarios to assesses and determine dermal and inhalation exposures. To assess occupational handler risk, the Agency used surrogate unit exposure data from both the proprietary Chemical Manufacturers Association (CMA) Antimicrobial Exposure Study (USEPA 1999: DP Barcode D247642) and the Pesticide Handlers Exposure Database (PHED) (USEPA 1998). For the occupational scenarios in which CMA data were insufficient, other data and methods were applied.

The duration of occupational handler exposure to OIT is expected to be intermediate-term (IT) for dermal exposures and short- and intermediate-term for inhalation exposures. Short-term dermal exposures were not assessed for most of the occupational handler scenarios because the

endpoint is based on dermal irritation. Instead, dermal irritation exposures and risks are mitigated, for most short-term dermal exposure uses, through the use of default personal protective equipment (PPE) based on the toxicity of the end-use products. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed to end-use products that result in classification of category I, II, or III for skin irritation potential is a long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and a chemical-resistant apron. Chemical-resistant gloves and a chemical-resistant apron can be eliminated for applicators and others exposed to OIT if, once diluted, the concentration in the diluted solution results in a toxicity category IV for skin irritation potential. Note that chemical-resistant eyewear is required if the end-use product is classified as toxicity category I or II for eye irritation potential.

As previously mentioned the use of PPE, specifically gloves, can reduce the risks for the majority of the occupational uses with short-term and intermediate-term dermal exposure. However, gloves are not a viable mitigation option for in-can preservative products, such as paints, because it is not feasible to label the end-use product with the biocide information. Short- and intermediate-term durations were assessed for dermal exposure to workers painting with in-can paint preservative products. Furthermore, gloves are not a viable mitigation option for machinists using biocide treated metalworking fluids. Short-, intermediate-, and long-term exposures were assessed for machinists working with metal working fluids. Typically the Agency does not conduct short-term dermal exposure assessments for handlers, when an irritation endpoint is selected, because the addition of PPE (gloves) generally mitigates risks of concern. However, because gloves (PPE) are not a viable mitigation option for workers painting with in-can preservative paint products and machinists working with metal working fluids, short-term dermal exposure assessments were conducted for these scenarios.

For intermediate-term dermal exposures (resulting in the potential for systemic effects), the PPE used by occupational users were assumed, at a minimum, to be a long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and goggles or face shield. For the professional painter scenario, no intermediate-term exposures were assessed because it is assumed that painters will not use OIT-preserved paint on a continuous basis.

Total MOEs (i.e., that account for combined exposures via dermal and inhalation routes) were not calculated for occupational use scenarios because the toxicological endpoints for dermal and inhalation exposures are different.

For more information on the assumptions and calculations for potential risks to occupational handlers refer to Section 8.0, Occupational Exposure and Risk, in the “Revised Octhilinone Risk Assessment for the Reregistration Eligibility Decision (RED) Document,” dated September 20, 2007 and the “Revised Occupational and Residential Exposure Chapter for Octhilinone (OIT) for the Reregistration Eligibility Decision (RED) Document (Case 2475),” dated September 17, 2007. Based on the representative use patterns of OIT, the exposure scenarios in Table 11 were assessed:

Table #11. OIT Representative Occupational Handler Exposure Scenarios

Representative Use	Method of Application	Exposure Scenario	Registration #	Application Rate
Material Preservatives				
Metalworking fluid	• Liquid pour • Liquid pump • Use of treated metalworking fluid	Handler (worker pouring preservative into fluid being treated): IT dermal; ST and IT inhalation Machinist: ST and IT dermal and inhalation	67071-6	0.0075% a.i. by weight (75 ppm a.i.)
Paint[1]	<u>Preservation of paint</u> • Liquid pour • Liquid pump <u>Professional painter</u> • Brush/roller • Airless sprayer	Handler: IT dermal; ST and IT inhalation Professional Painter: ST dermal and inhalation	67071-31	0.23% a.i. by weight (13.8 lb product/1000lb paint x 16.84% a.i. in product)
Plastics and vinyl[2]	• Liquid pour • Liquid pump	Handler: IT dermal; ST and IT inhalation	81348-8	0.4% a.i. by weight (2% product by weight of material treated x 20% a.i. in product)
Leather	• Liquid pour • Metering pump	Handler: IT dermal; ST and IT inhalation	707-121	0.019% a.i. by weight hides (3,530 ppm product in hides (wet weight) x 5.5% a.i. in product)
Textiles	• Liquid pour • Liquid pump	Handler: IT dermal; ST and IT inhalation	67071-6	0.12% a.i. by weight (0.25% product by weight of material treated x 46.5% a.i. in product)
Mattresses	• Mechanical metering pump	Handler: IT dermal; ST and IT inhalation	81348-8	0.4% a.i. by weight (2% product by weight of material x 20% a.i. in product)
Industrial Processes and Water Systems				
Cooling tower waters[3]	N/A	N/A	707-100	N/A

Representative Use	Method of Application	Exposure Scenario	Registration #	Application Rate
Wood Preservatives				
Wood preservative	• High Pressure Spray	Handler: IT dermal; ST and IT inhalation	73612-1	0.096% a.i. solution (80 liters product/ 1000 liters water x 1.2% a.i. in product)

[1] Preservation of paint is assumed to be representative of various exposures related to the incorporation of OIT into liquid substances during production (including sealants, adhesives, and other viscous materials) as well as addition of OIT to solid products where addition of product occurs during manufacture; e.g., carpets, molded goods, etc.).
[2] Assumed to be representative of exposures related to addition of OIT to plastics, polymers, vinyl, and similar products during the manufacturing process.
[3] Use directions on label are described for manufacturing use product only; no end uses are provided. Therefore, no exposure assessment was conducted for this scenario.

c. Occupational Handler Risk Summary

The occupational handler risk assessment included both inhalation and dermal exposure scenarios. The target MOE for short- and intermediate-term inhalation exposures is 30. For dermal exposures, the target intermediate-term MOE is 100.

As previously mentioned, short-term dermal exposures were not assessed for most of the occupational uses because dermal irritation via short-term exposures is mitigated with the use of chemical resistant gloves (PPE). However, the Agency can not require the use of gloves (PPE) on in-can paint preservative labels. Therefore, a short-term risk assessment was conducted for in-can paint application by professional handlers.

Materials Preservation & Wood Preservation Uses

The MOEs for the occupational handler use scenarios for materials preservation and wood preservation were above their target MOEs (target MOE of 100 for IT dermal; target MOE of 30 for ST/IT inhalation exposures) except for the following scenarios:

- *Preservation of Plastics & Vinyl: Liquid Pour*
  (IT dermal MOE = 39) (ST/IT inhalation MOE = 2)

- *Preservation of Plastics & Vinyl: Liquid Pump*
  (IT dermal MOE = 83)
  (ST/IT inhalation MOE = 2)

- *Paint Preservation: Liquid Pour*
  (IT dermal MOE = 67)
  (ST/IT inhalation MOE = 4)

- *Paint Preservation: Liquid Pump*
  (ST/IT inhalation MOE = 3)

- *Textiles Preservation: Liquid Pour*
  (ST/IT inhalation MOE = 14)

For further information regarding the short- and intermediate-term risks to occupational handlers exposed to OIT materials preservatives and wood preservatives, refer to Table 12.

Table #12. Short- and Intermediate-Term Exposures & Risks Associated with Occupational Handlers (Materials & Wood Preservation)

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)		App. Rate	Quantity Handled/ Treated per day	Absorbed Daily Dose (mg/kg/day)			MOE[e]	
		Dermal[a]	Inhalation				ST/IT Inhalation[c] mg/kg/day	ST/IT Air Conc[d] mg/m^3	IT Dermal (Target MOE = 100)	ST/IT Inhalation (Target MOE = 30)
Preservation of metalworking fluid	Liquid pour	0.184	0.0085	0.0075% a.i. by weight	2,502 lbs (300 gal)	0.00049	2.3E-05	0.000199	12,000	370
	Liquid pump	0.312	0.00348	0.0075% a.i by weight	2,502 lbs (300 gal)	0.00084	9.3E-06	0.000082	7,100	890
Preservation of plastics and vinyl	Liquid pour	0.135	0.00346	0.4% a.i. by weight	20,000 lbs (2,000 gal)	0.15	0.0040	0.034600	**39**	**2**
	Liquid pump	0.00629	0.000403	0.4% a.i. by weight	200,000 lbs (20,000 gal)	0.072	0.0046	0.040300	**83**	**2**
Preservation of paint	Liquid pour	0.135	0.00346	0.23% a.i. by weight	20,000 lbs (2,000 gal)	0.090	0.0023	0.019895	**67**	**4**
	Liquid pump	0.00629	0.000403	0.23% a.i. by weight	200,000 lbs (20,000 gal)	0.041	0.0026	0.023173	140	**3**
Preservation of textiles	Liquid pour	0.135	0.00346	0.12% a.i. by weight	10,000 lbs	0.023	0.00059	0.005190	260	**14**
	Liquid pump	0.00629	0.000403	0.12% a.i. by weight	10,000 lbs	0.0011	6.9E-05	0.000605	5,500	120
Preservation of mattresses	Liquid pump	0.00629	0.000403	0.4% a.i. by weight	2,860 lbs (1,300 kg)	0.0010	6.6E-05	0.000576	5,800	130
Application of paint by professionals	Brush/ roller	NC[b]	0.28	0.23% a.i. by weight	50 lbs (5 gal)	NC	0.00046	0.004025	NC	**25**

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)		App. Rate	Quantity Handled/ Treated per day	Absorbed Daily Dose (mg/kg/day)			MOE[e]	
		Dermal[a]	Inhalation				ST/IT Inhalation[c] mg/kg/day	ST/IT Air Conc[d] mg/m^3	IT Dermal (Target MOE = 100)	ST/IT Inhalation (Target MOE = 30)
Mixing, loading, and applying wood preservative solution	High pressure/high volume spray	2.5	0.12	0.096% a.i.	2,195 lbs (263 gal)	0.048	0.00036	0.0032	130	200

ST = short-term, IT = intermediate-term, NC = Not conducted

a With the exception of the scenario for application of paint, all dermal unit exposure estimates used for occupational handler scenarios represent exposures incurred assuming the use of PPE (at least a long-sleeve shirt and long pants plus gloves), as specified on the product labels. For the application of paint by professional painters, dermal exposures were calculated for baseline dermal exposures (long-sleeve shirt, long pants, and *no* gloves).

b NC = not conducted. Short-term dermal exposures during the application of paint resulting in the potential for dermal irritation are evaluated in Section 6.5. Intermediate-term dermal exposures during the application of paint are not assessed because it was assumed that professional painters will not use OIT-preserved paint on a continuous basis.

c Absorbed Daily dose (mg/kg/day) = [unit exposure (mg/lb ai) * application rate (%a.i. by weight) * quantity treated or handled (lb/day) / Body weight (70 kg).

d Air conc (mg/m3) = dose (mg/kg/day) x 70 kg x light activity inhalation rate (day/ 8m^3)

e MOE = NOAEL (mg/kg/day) / Absorbed Daily Dose [Where IT dermal NOAEL = 5.95 mg/kg/day and the ST/IT inhalation 8 hr HEC = 0.073 mg/m^3 and ST/IT inhalation 6 hr HEC = 0.098 mg/m^3 for professional painter]

Leather Processing

The potential for occupational exposure, resulting from leather processing, was based on the loading of the product by open pouring or connecting/disconnecting a metering pump. Chemical-specific exposure data were not submitted to support leather processing. Therefore, a screening-level assessment was developed using surrogate data to determine the potential risks associated with leather processing.

The most representative exposure data available for industrial uses are the monitoring data from the CMA Antimicrobial Exposure Assessment Study (US EPA 1999: DP Barcode D247642). The liquid open pour and liquid pump data from the preservative loading were used to develop the screening-level assessment. The dermal UEs of 0.135 mg/lb a.i. for liquid open pour and 0.00629 mg/lb a.i. for liquid pump are both based on only 2 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves (UE are not available for the "no glove" scenarios). The inhalation UEs are based on the same 2 replicates. The inhalation UE for open pour is 0.00346 mg/lb a.i. and the UE for liquid pump is 0.000403 mg/lb a.i. Although these exposure scenarios are based on minimal replicates, the exposure values are similar to those found in PHED for similar scenarios.

Table 13 presents the potential, non-cancer, dermal and inhalation risks for the leather processing use of OIT. The dermal and inhalation handler MOEs for leatherworking are not of concern.

Table #13. Short and Intermediate-term Dermal and Inhalation Risks Associated With Occupational Handling of OIT in Leatherworking

Equipment	Exposure Scenario	Unit Exposures (mg/ lb a.i.)		Amount Handled (lbs a.i./day)	Daily Dose (mg/kg/day)			MOE [d]	
		Dermal	Inhal.		IT Dermal [a]	ST/IT Inhal Dose [b]	ST/IT Inhal Air Conc.[c]	IT Dermal Target MOE= 100	ST/IT Inhalation Target MOE= 30
Raceway	Open pour – liquid	0.135	0.00346	2.36	0.0046	1.2E-04	0.0010	1,300	72
	Metering pump	0.00629	0.000403	12.6 (ST) 3.8 (IT)	0.00034	7.3E-05 (ST) 2.2E-05 (IT)	0.00064 (ST) 0.00019 (IT)	17,000	120 (ST) 380 (IT)
Mixer	Open pour – liquid	0.135	0.00346	2.36	0.0046	1.2E-04	0.0010	1,300	72
	Metering pump	0.00629	0.000403	2.62	2.3E-04	1.5E-05	0.00013	25,000	560
Tanning drum	Open pour – liquid	0.135	0.00346	2.36	0.0046	1.2E-04	0.0010	1,300	72
	Metering pump	0.00629	0.000403	5.0	4.5E-04	2.9E-05	0.00025	13,000	290

a Dermal Dose (mg/kg/day) = Dermal UE (mg/lb ai) x amount handled (lb ai/day) / 70kg .
b Inhalation Dose (mg/kg/day) = Inhalation UE (mg/lb ai) x amount handled (lb ai/day) / 70kg .
c Air conc (mg/m3) = Inhal dose (mg/kg/day) x 70 kg x Inhal rate (day /8m^3)
d MOE = NOAEL / Dose. Where IT dermal NOAEL = 5.95 mg/kg/day, and ST and IT inhalation HEC = 0.073 mg/m^3.

Professional Painter

The metal working fluids (machinist) and professional painter scenarios were assessed and are discussed separately because of the route of exposure that is applicable to these uses, and because it is not feasible to mitigate these risks with personal protective equipment (PPE) restrictions. The handler is assumed to be coming into contact with these materials after they have been preserved with OIT.

There is the potential for dermal and inhalation exposures to professional painters handling paint that has been preserved with OIT. The methods of application include painting with a brush or roller as well as airless spraying. For the professional painter scenario, intermediate-term exposures were not assessed because it was assumed that painters will not use OIT-preserved paint on a continuous basis.

Dermal Exposure (Irritation)

The potential for short-term (ST) dermal exposure during professional painting activities to OIT resulting in dermal irritation was assessed. Intermediate-term (IT) exposures were not assessed for the professional painter because it was assumed that not all of the paint used by a professional on an intermediate-term basis is treated with OIT.

The short-term exposure estimate based on surface area (i.e., as mg a.i. per cm^2 of skin area exposed) was derived using the same approach presented previously in Section 4.b.i of this document for the residential painter. Because the inputs for the professional painter are identical to those used for the residential painter, the estimated exposure and MOE for brush/roller and airless spray applicators are also the same. There are no risks of concern for short-term dermal exposure because the calculated MOE is10 (target MOE = 10).

Table #14. Short-term Dermal Exposures & MOEs for Occupational Painter

Exposure Scenario	% ai	Film thickness (mg/cm^2)	Paint Matrix Effect (%)	Exposure (mg/cm^2)	Dermal MOE (Target MOE is 10) [a]
Painter	0.23%	10.3	28%	0.0067	10

a MOE = NOAEL (mg/cm^2) / Potential exposure (mg/cm^2) [Where: NOAEL for short-term dermal irritation = 0.0674 mg/cm^2, Table 3.2].

Inhalation Exposure (via brush/roller)

The application of paint via brush/roller is presented in table X, above. The MOE for the application of paint via brush/roller is below the target MOE of 30 (MOE =25), indicating a risk of concern.

Inhalation Exposure (via airless sprayer)

The Agency used the same exposure data (PHED & NPCA) and assumptions as described in the Residential Inhalation Exposure portion of this document (Section 4.b.1) to determine the inhalation MOEs for paint application via an airless sprayer. It was assumed that it could take professional applicators 6 hours to apply paint using an airless sprayer.

The inhalation exposure MOEs for paint application via airless sprayer, in which PPE are not feasible, are below the target MOE of 30 (MOE = 1 using PHED data; MOE = 2 using NPCA data). Therefore, paint application via airless sprayer poses as an inhalation risk of concern to occupational handlers.

Table 15 provides further information on the inhalation doses and MOEs for professional painter exposure via airless sprayer.

Table #15. Short-term Inhalation Exposures and MOEs for Professional Painter Using an Airless Sprayer

Method of Application	App.Rate (% a.i.)	Inhalation Unit Exposure PHED (mg/m^3/%ai) NCPA (mg/m^3)	Air Conc. (mg/m^3)[a]	HEC (mg/m^3)	Route Specific MOE (ST) [b]
Airless Sprayer (PHED)	0.23%	0.681	0.16	0.10 at 6 hrs	**1**
Airless Sprayer (NPCA)	0.23%	22.91	0.053	0.10 at 6 hrs	**2**

[A] Air con (mg/m3) = App Rate (%ai) x UE (mg/m3/%ai)
(Note that the %ai in the PHED UE is in terms of whole numbers, not fraction (i.e., 0.23 not 0.0023)
Air con (mg/m3) = App Rate (%ai) x UE (mg/m3i)
(Note that the %ai using the NCPA UE is in terms of fraction (i.e., 0.0023)
[b] Inhalation MOE = HEC (mg/m^3) / Air conc. (mg/m^3). Target inhalation MOE is 30.

Metal Working Fluids (machinists)

The metal working fluids (machinist) and professional painter scenarios were assessed and are discussed separately because of the route of exposure that is applicable to these uses, and because it is not feasible to mitigate these risks with personal protective equipment (PPE) restrictions. The handler is assumed to be coming into contact with these materials after they have been preserved with OIT.

There is the potential for dermal and inhalation exposure when a worker handles treated metalworking fluids. This route of exposure occurs after the chemical has been incorporated into the metalworking fluid and the machinist is using/handling the treated end use product. Tables 16 and 17 provide further information on the dermal and inhalation doses and MOEs for machinist exposure to metalworking fluids. The MOE values are above the target MOEs and therefore, neither dermal or inhalation risks of concern.

Table #16. Short- and Intermediate-term Dermal Exposures and MOEs for Machinist Exposure to Metalworking Fluids

Exposure Scenario	% ai	Hand Surface Area (cm^2/event)	Film thickness (mg/cm^2)	Frequency (event/ day)	Exposure [a]	Dermal MOE (Target MOE is 10 for ST and 100 for IT) [b]
Machinist - two hand immersion	0.0075%	N/A	10.3 for ST	N/A	7.7E-4 mg/cm^2	87
		840	1.75 for IT	1	0.0016 mg/kg/day	3,800

a For ST, exposures are calculated as a.i. per area of skin exposed (mg/cm^2) = (% active ingredient x film thickness mg/cm^2 (10.3 for ST exposure). For IT, exposures are calculated as an Absorbed Daily Dose normalized to body weight (mg/kg/day) = [(% active ingredient x hand surface area (cm^2/event) x film thickness (mg/cm^2) × Frequency (event/day)] / Body weight (70 kg).

b MOE = NOAEL (mg/kg/day) / exposure, where exposure is a.i. per skin area (mg/cm^2) for ST and Absorbed Daily Dose (mg/kg/day) for IT. [Where: short-term NOAEL = 0.0674 mg/cm^2 and intermediate-term NOAEL = 5.95 mg/kg/day for dermal exposures, Table 3.2.]

Table #17. Short- and Intermediate-term Inhalation Exposures and MOEs- Exposure to Metalworking Fluids treated with OIT (Machinist)

Exposure Scenario	% a.i.	OSHA PEL (mg/m^3)	ST/IT Daily Exposure[a] (mg/m^3)	ST/IT Inhalation MOE (Target MOE = 30) [b]
Machinist	0.0075%	5	0.000375	200

a Daily exposure or air concentration (mg/m^3) = % active ingredient x OSHA PEL (mg/m^3).
b MOE = 8 hr HEC (0.073 mg/m^3) / air concentration (mg/m^3)

d. Occupational Post-application Risk Summary

No occupational post-application exposures are assumed to occur for the occupational handler use scenarios summarized in Table 12. Any post-application exposures from these uses are expected to occur in a residential setting, which are described in the residential exposure portion of this document.

9. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to OIT. EPA consulted the following sources of information for human poisoning incidents related to OIT use: (1) OPP Incident Data System (IDS)- The Office of Pesticide Programs (OPP) Incident Data System contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; (2) California Department of Pesticide Regulation (1982-2004)- The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982; (3) National Pesticide Information Center (NPIC)- NPIC is a toll-free information service supported by OPP That provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991.; and (4) Published Incident Reports- Some incident reports associated with OIT related human health hazard are published in scientific literature.

Dermal exposure is the primary exposure route for all of the reported incidences and most are related to irritation and/or an allergic type reaction. The most common symptoms reported for cases of dermal exposure were skin irritation/burning, rash, itching, redness and blistering. Allergic contact dermatitis has also been reported.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The majority of the uses for OIT are considered indoor and to have minimal to no environmental exposure potential following product use, with the exception of the antisapstain wood treatment use and the once-through cooling tower use. However, an ecological risk assessment was not conducted for the once-through cooling tower use because the registrant has indicated that they will voluntarily cancel this use. In order to be eligible for reregistration, the once-through cooling tower use must be removed from all product labels. An environmental risk assessment is needed for the antisapstain wood treatment use because this use has a high potential for

environmental exposure. However, an environmental risk assessment could not be conducted because of outstanding data that are required to conduct a complete antisapstain wood treatment risk assessment. A Tier I, "down-the-drain" model was preformed to simulate industrial process wastewater releases, resulting from the uses of OIT as a material preservative.

The following risk characterization is intended to describe the magnitude of the estimated environmental risks for OIT use sites and any associated uncertainties. For a detailed discussion of all aspects of the environmental risk assessment, refer to Section 9.0, Environmental Fate, and Section 10.0, Environmental Risk, in the "Revised Octhilinone Risk Assessment for the Reregistration Eligibility Decision (RED) Document," dated August 20, 2007; the "Environmental Fate Assessment of Octhilinone," dated March 30, 2007; and the "Transmittal of Octhilinone (OIT) RED Ecological Hazard and Environmental Risk Assessment Chapter-Case Number 2425," date March 7, 2007.

1. Environmental Fate and Transport

The environmental fate assessment for OIT was based on guideline data and reports required by the Agency for an environmental fate assessment; conclusions and values provided from the Environmental Protection Agencies Office of Water (OW) "down-the-drain" modeling; and the Environmental Protection Agencies Estimation Programs Interface (EPI) Suite. For additional information on the environmental fate assessment, please refer to the "Environmental Fate Assessment of Octhilinone," dated March 30, 2007.

Based on the out-put values from the EPI Suite model and additional resources, the octanol/water partition coefficient is fairly low (Kow = 3.62). Therefore, OIT is not likely to bio-accumulate in various aquatic organisms. OIT is stable and persistent in water under abiotic conditions with a half life of greater than 30 days. OIT does not migrate much and the chemical binds strongly with soil. Therefore, OIT is expected to remain on surface soils, which may result in contamination of surface water. OIT's degradation pathway appears to be through microbial biodegradation in surface soils under aerobic and anaerobic conditions within 120 days. These values suggest that OIT is expected to biodegrade fairly fast in the environment and any contamination would be short lived. The vapor pressure of OIT is low (3.68×10^{-5} mm Hg @ 25 ^{o} C) and the vapor is not likely to be persistent in air (air half life = 3.3. hours).

The data that were available and reviewed by the Agency addressed various properties of OIT such as the stability in water, biodegradation, leaching and behavior in soils. Based on the results of these studies, when OIT is in water it is likely to be stable and persistent (MRID 44723201) and biodegrade slower than it would in soils (Technical Report 23-17-4). OIT is immobile in soils and, therefore, is not likely to contaminate groundwater (Technical Reports 23-72-3 and 3923-74-38). In addition, based on the data provided in a leaching and soil metabolism study, OIT is not likely to migrate into groundwater. OIT biodegrades in soil medium to less than 50% over the course of 120 days (Technical Report 3923-75-11).

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics and pesticide use data. A summary of the submitted data is provided below.

a. Environmental Toxicity

Toxicity to Birds

Available data indicate that OIT is slightly toxic to birds on an acute oral basis and slightly to relatively non-toxic to birds on a sub-acute dietary basis. Therefore, an avian environmental hazard statement for birds is not required on manufacturing use product labels.

Toxicity to Terrestrial Animals

Based on the results of mammalian studies conducted to meet human toxicity data requirements, OIT exhibits moderate oral, dermal, and inhalation toxicity (toxicity category III). For primary eye irritation, OIT is moderately irritating (toxicity category III). OIT is corrosive to the skin and is a dermal sensitizer.

Toxicity to Aquatic Animals

On an acute basis OIT is very highly toxic to rainbow trout, estuarine/marine invertebrates, shrimp & oysters; and is highly toxic to bluegill sunfish, freshwater invertebrates, and estuarine/marine fish.

Because acute toxicity values to fish, aquatic invertebrate, estuarine/marine aquatic fish, mollusk and shrimp are <1.0 mg/L, the environmental hazard section of OIT labels must state, "This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp."

The guideline requirement for a chronic fish early life stage toxicity study (OPPTS 850.1400/ 72-4) is not fulfilled due to missing raw data (MRID 41909301). Also, the guideline requirement for chronic aquatic invertebrate data has not been fulfilled because the maximum allowable toxicant concentration (MATC) could not be determined (>0.074 mg/L) (MRID 41909401). Additional chronic aquatic toxicity studies are not required to be repeated at this time, but are held in reserve pending the results of the Tier I risk assessment for the treated lumber antisapstain use.

Toxicity to Plants

For toxicity to plants, non-target plant phytotoxicity testing is required for pesticides when certain conditions of use and environmental fate apply. The use of OIT as an antisapstain wood treatment may result in chemical leachate from treated wood into the aquatic environment. The guideline requirements for testing toxicity to plants are partially fulfilled for the green algae

toxicity test in which growth inhibition was shown. However, confirmatory data are required to conduct a Tier I risk assessment for the treated lumber antisapstain use.

A summary of the submitted acute ecological toxicity data, avian sub-acute dietary toxicity data, chronic freshwater fish toxicity data and aquatic plant toxicity data for OIT are provided in Tables 18, 19, 20 and 21, respectively.

Table #18. Acute Ecological Toxicity

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/kg)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Birds (Acute Oral Toxicity)					
Bobwhite quail (*Colinus virginianus*)	Octhilinone 98.5%	LD_{50} = 660 NOAEL = ND (a.i.)	Slightly toxic	Yes - 21-day test duration - 19 weeks of age	416080-01
	Octhilinone 95.9%	LD_{50} = 384 NOAEL = 171 (a.i.)	Moderately toxic	Yes - 14-day test duration - 21 weeks of age	448590-01
	Octhilinone 88.7%	LD_{50} = 346 (a.i.)	Moderately toxic	Yes	00026809
	Octhilinone RH-893 (% purity unknown)	LD_{50} = 565 (M) and 498 (F)	Slightly toxic	No	86-870001877 (Ecotox data)
Mallard duck (*Anas platyrhynchos*)	Octhilinone RH-893 (% purity unknown)	LD_{50} > 1000	Slightly toxic	No	86-870001877 (Ecotox data)
Freshwater Fish (Acute Toxicity)					
Rainbow Trout (*Oncorhynchus mykiss)*	Octhilinone 98.5%	LC_{50} = 0.047 NOAEC = 0.023 (a.i.)	Very highly toxic	Yes - 96-hr test duration - flow-through test system	416080-05

	Octhilinone 96%	LC_{50} = 0.05 LOEC = 0.05 NOEC = < 0.05 (a.i.)	Very highly toxic	No - 96-hr test duration - static renewal test system - toxic effects and death at all treatment levels - small aquaria	439357-02
Rainbow Trout (O*ncorhynchus mykiss* ,formerly *Salmo gairdneri*)	Octhilinone 90%	LC_{50} = 0.0655 (a.i.)	Very Highly toxic	No - 96-hr test duration - static test system	00026805
Bluegill sunfish (*Lepomis macrochirus)*	Octhilinone 98.5%	LC50 = 0.18 (a.i.)	Highly toxic	Yes - 96-hr - flow-through test system	416080-04
	Octhilinone 96%	LC_{50} = 0.16 NOAEC = 0.07 (a.i.)	Highly toxic	Yes - 96-hr test duration - static renewal test system	439357-03
	Octhilinone 90%	LC_{50} = 0.196 (a.i.)	Highly toxic	No - 96-hr test duration - static test system	00026805
	Octhilinone 90%	LC_{50} = 0.203 (a.i.)	Highly toxic	No - 96-hr test duration - static test system	00026805
Fathead minnow (*Pimephales promelas*)	Octhilinone 90%	LC_{50} = 0.140 (a.i.)	Highly toxic	No - 96-hr test duration - static test system	00026805
Golden shiner (*Notemigonus crysoleucas*)	Octhilinone 90%	LC_{50} = 0.154 (a.i.)	Highly toxic	No - 96-hr test duration - static test system	00026805

Freshwater Invertebrates (Acute Toxicity)					
Waterflea (*Daphnia magna)*	Octhilinone 98.5%	EC_{50} = 0.32 NOAEC = 0.21 (a.i.)	Highly toxic	Yes - 48-hr test duration - flow-through test system	416080-06
	Octhilinone 96%	EC_{50} = 0.107 NOAEC = 0.055 (a.i.)	Highly toxic	No - 48-hr test duration - static test system - total hardness above guideline - small test aquaria	439357-04
	Octhilinone 88.7%	LC_{50} = 0.18 (a.i.)	Highly toxic	Yes - 48-hr test duration - static test system	00026806 (Ecotox data No. 86-870001884)
Estuarine & Marine Organisms (Acute Toxicity)					
Sheepshead minnow (*Cyprinodon variegatus*)	Octhilinone 98.5%	LC_{50} = 0.16 NOAEC = 0.0.054 (a.i.)	Highly toxic	Yes - 96-hr test duration - flow-through test system	416080-07
Mysid shrimp (*Mysidopsis bahia)*	Octhilinone 98.5%	LC_{50} = 0.071 NOAEC = <0.034 (a.i.)	Very highly toxic	Yes - 96-hr test duration - flow-through test system	416080-08
Eastern oyster (*Crassostrea virginica*)		Octhilinone 98.5%	Very highly toxic	Yes - 96-hr test duration - flow-through test system	417007-01

Table #19. Sub-acute Oral Toxicity of Octhilinone to Birds

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/kg)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Bobwhite quail (*Colinus virginianus)*	Octhilinone 98.5%	LC_{50} (diet) = >3267 NOAEC = 1288 (a.i.)	Slightly toxic	Yes - 8-day test duration - 11 weeks of age	416080-02
	Octhilinone 96%	LC_{50} (diet) = 2542 NOAEC = 310 (a.i.)	Slightly toxic	No - 12-day test duration - 10 days of age - control mortality 20% - inadequate housing	439357-01
	Octhilinone 88.7%	LC_{50} (diet) >5620 (a.i.)	Relatively nontoxic	Yes - 8-day test duration	00026808
Mallard duck (*Anas platyrhynchos)*	Octhilinone 98.5%	LC_{50} (diet) = 1215 NOAEC = ND (a.i.)	Slightly toxic	Yes - 8-day test duration - 5 days of age	416080-03
	Octhilinone 88.7%	LC_{50} (diet) = >5620 (a.i.)	Relatively nontoxic	Yes	00026807

Table #20. Chronic Toxicity of Octhilinone to Freshwater Organisms

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Fathead Minnow (*Pimephales promelas*)	Octhilinone 98.5%	LOAEC = ND NOAEC = ND MATC >8.5 and < 0 .018; 0.012 geo. Mean (a.i.)	No - 35-day test duration - early-life stage - flow-through test system -relative S.D. for fish weight in one control replicate unacceptable (53%)	419093-01
Waterflea (*Daphnia magna*)	Octhilinone 98.5%	NOAEC = 0.074 (a.i.)	No - 21-day test	419094-01

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
			duration - life-cycle - flow-through test system - MATC could not be determined - raw data missing	

Table #21. Toxicity of Octhilinone to Aquatic Plants

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Green alga (*Selenastrum capricornutum)*	Octhilinone 99.2%	EC_{50} (120-hour, cell density) = 0.015) NOEC (120-hour cell density) = <0.011	YES - growth inhibition - 120-hr test duration - static test system	440710-01

b. Ecological Exposure and Risk

The Agency has evaluated the industrial processes wastewater releases (resulting from the use of OIT as a materials preservative) and antisapstain wood preservative uses being considered for reregistration. The majority of OIT uses are classified as "indoor" and to have minimal or no environmental impact; therefore, an ecological risk assessment was not needed for the majority of these uses. However, a Tier I down-the-drain risk assessment was needed to simulate industrial process wastewater releases. A Tier I ecological risk assessment is also required for the treated lumber antisapstain use. However, the antisapstain ecological risk assessment could not be conducted as a result of data deficiencies and unavailable data endpoints.

Industrial Waste Water Releases

The high stability of OIT in water and its long aerobic and anaerobic half lives triggered the need for Tier I "down-the-drain" modeling and a "down-the-drain" risk assessment. The "down-the-drain" model was utilized to provide expected environmental concentrations (EEC's) for OIT that may be flushed down-the-drain following use of materials treated with OIT and

following industrial applications of OIT treated materials. The "down-the-drain" model provided the following environmental concentrations (EEC's):

Acute – 0.006 ppb (0.000006 ppm)
Chronic - 0.080 ppb (0.00008 ppm)

The expected EEC's are worst-case estimates assuming that 100% of OIT, produced for antimicrobial use, is discharged down-the-drain. The worst-case scenario was used for the Tier I assessment to generate risk quotients. The model does not account for formulation dilution of active ingredient or for reduced efficacy following use. Table 22 provides the generated risk quotients and Table 23 provides the risk presumption categories for terrestrial animals, aquatic organisms, and terrestrial and aquatic plants.

Table #22. Risk Quotients for OIT Industrial Processes and Waste Water Releases using the Down-the-Drain Model

Species	Toxicity Value (ppm)	RQ
Rainbow trout	0.05 LC50	0.0016
Daphnia magna acute chronic	0.18 EC50 0.07 NOAEC	0.0004 0.00009
Sheepshead minnow	0.16 LC50	0.0005
Mysid shrimp	0.07 EC50	0.0014
Eastern oyster	>0.06 EC50	0.0013
Green algae	0.02 EC50	0.0040

Table #23. Risk Presumption Categories

Risk Presumption for Terrestrial Animals	**LOC**
Acute: Potential for acute risk for all non-target organisms	>0.5
Acute Restricted Use: Potential for acute risk for all non-target organisms, but may be mitigated through restricted use classification	>0.2
Acute Endangered Species: endangered species may be adversely affected by use	>0.1
Chronic Risk: potential for chronic risk may warrant regulatory action	>1
Risk Presumption for Aquatic Organisms	**LOC**
Acute: Potential for acute risk for all non-target organisms	>0.5
Acute Restricted Use: Potential for acute risk for all non-target organisms, but may be mitigated through restricted use classification	>0.1
Acute Endangered Species: endangered species may be adversely affected by use	>0.05
Chronic Risk: potential for chronic risk may warrant regulatory action	>1
Risk Presumption for Terrestrial and Aquatic Plants	**LOC**
Potential for risk for all non-endangered and endangered plants	>1

No acute, chronic, or endangered species level of concerns (LOCs) are exceeded for aquatic animals and green algae. However, the risk assessment is incomplete due to missing non-target plant ecotoxicity endpoints. Plants are the most sensitive species tested. Therefore, the full compliment of plant toxicity tests are required to evaluate toxicity to other non-target plant groups. Terrestrial animals are not expected to be exposed to residues greater than those predicted by the "down-the-drain" model.

Antisapstain Wood Treatment Use

As previously mentioned, an antisapstain wood treatment ecological risk assessment for terrestrial and aquatic organisms could not be conducted for OIT as a result of data deficiencies. Soil Koc and wood leaching rate data are required in order to conduct the Tier I antisapstain environmental risk assessment. It is important to note that surface water monitoring data, that can obtain expected environmental concentrations (EECs), may be submitted in lieu of an antisapstain model. Due to the high toxicity of OIT to aquatic organisms, chronic fish and aquatic invertebrate studies are needed. However these studies will be held in reserve pending the results of the Tier I antisapstain risk assessment. Outstanding plant toxicity studies and confirmatory ecological toxicity data must be submitted to the Agency in order to conduct an antisapstain wood treatment risk assessment. These data needs are outlined in Chapter V, Table X of this document.

Non-target Insects (Honeybee)

Honeybees could potentially be exposed to pesticide residues if treated wood is used to construct hives or hive components. These residues may be toxic to the bees or result in residues in honey or other hive products intended for human use/consumption. Therefore, a special honeybee study is required for all wood preservative uses unless a statement prohibiting the use of treated wood in hive construction is added to the label such as, "Wood treated with OIT shall not be used in the construction of beehives." This study is a combination of Guidelines 171-4 and 850.3030 (see information regarding residue data requirements for uses in beehives in the residue chemistry section of 40 CFR part 158). Numbers of bees used in this study and methods for collection/introduction of bees into hives, feeding, and observations for toxicity and mortality should be consistent with those described in OPPTS Guideline 850.3030, "Honey Bee Toxicity of Residues on Foliage." The toxicity portion of this study is in lieu of the honeybee contact LD50 test.

c. Risk to Listed Species

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 IIB, 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. The active ingredient uses of OIT, with the exception of the industrial waste water discharges and the antisapstain wood preservation uses, fall into this category.

Risks to aquatic animals and green algae were not identified, using Tier I "down-the-drain" modeling to assess potential exposure from industrial waste water discharges. However, the industrial waste water discharges assessment is considered to be incomplete due to missing non-target plant eco-toxicity endpoints. The full compliment of plant toxicity tests are required to confirm that green algae is the most sensitive non-target plant species. Terrestrial animals are not expected to be exposed to residues greater than those predicted by the "down-the-drain" model. A No Effect determination is made for terrestrial and aquatic animal species from "indoor" OIT uses. However, the Agency defers making an endangered species determination for terrestrial and aquatic plants from "indoor" uses, as a result of the industrial waste water treatment use, of OIT until after receipt of outstanding data.

A Tier I antisapstain model to assess potential exposure from treated antisapstain wood was not conducted due to the lack of OIT wood leaching rate data and soil Koc's. An environmental monitoring study of runoff from antisapstain treatment facilities is suggested to address the potential risks and to provide EECs for a risk assessment as an alternative to the antisapstain Tier I model. The Agency defers making an endangered species determination for

the antisapstain use of OIT until additional data and modeling refinements are available. At that time, an environmental exposure assessment of the antisapstain use of OIT will be conducted, and the risks to Listed Species will be considered.

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 OIT as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of all supported products containing OIT.

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 OIT. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient OIT, the Agency has sufficient information on the human health and ecological effects of OIT 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 OIT-containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measure outlined in this document is adopted; and (iii) label amendments are made to reflect this measure. Label changes are described in Section V. Appendix A summarizes the uses of OIT 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 OIT 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 OIT, the Agency has determined that OIT products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of OIT. If all changes outlined in this document are incorporated into the product labels, then all current risks for OIT will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, the EPA worked with stakeholders and the public to reach the regulatory decision for OIT. During the public comment period, which closed on August 17, 2007, the Agency received comments from the OIT Task Force Committee, in response to the EPA's draft OIT risk assessment (RA) and supporting science documents. The comments included suggestions for using AMEM exposure modeling for the vinyl flooring assessment; and, the submission of additional paint exposure data to further characterize the airless sprayer exposure assessment. The task force also suggested the use of a chemical specific dermal bioavailability data/matrix effect study which impacted the painter dermal MOEs found in the draft OIT Risk Assessment. Other comments included suggestions

for additional personal protection equipment (PPE) to reduce possible exposure risks to wood treatment workers. The Agency's response to these comments has been incorporated, as necessary, into the revised OIT Risk Assessment and revised supporting science chapters. These revised documents are available on the U.S. Federal Government's web docket at: http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0414). A Response to Comment document will be made available on the public docket in the future. In addition, comments received by the registrants during the Phase I, Error Only Comments Period, of the RED process are available on the docket. The Agency is providing a 60-day public comment period on this RED document.

C. Regulatory Position

a. Determination of Safety to U.S. Population

The Agency has determined that the tolerances for OIT, with amendments and changes specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of OIT. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of OIT.

An acute/chronic dietary risk assessment and an aggregate dietary exposure and risk assessment were not conducted for OIT because the use patterns are not expected to result in acute or chronic dietary exposure and toxicity endpoints were not identified. The Agency did address the possibility of indirect food contact resulting from adhesives preserved with OIT. It was determined that dietary exposure resulting from possible indirect food contact is not expected and that a complete dietary assessment was not needed. All labels with the adhesive use pattern contain language that either specify the type of adhesive (e.g., wallpaper adhesive); or, the labels state that the products are for non-food use contact. Therefore, there are no indirect food contact dietary risks of concern. A dietary risk assessment was not conducted for the once-through cooling tower use because the registrant has indicated that they will voluntarily cancel this use. In order to be eligible for reregistration, this use must be removed from all product labels.

For adults and children, an aggregate assessment of incidental oral, dermal, and inhalation exposures was not performed across routes of exposure because toxicity endpoints of concern were derived from separate toxicity studies. However, the Agency did aggregate route specific exposures for incidental oral scenarios for children, and dermal scenarios for children and adults. An aggregate assessment was conducted for dermal exposures of adults to clothing and mattresses. The total aggregate MOE for dermal exposure to adults (MOE = 42) is above the target MOE of 10 and is not of concern. An aggregate assessment was also conducted for dermal exposures of children to treated clothing, mattresses, and vinyl tiles. The total aggregate MOE for dermal exposures to children (MOE = 42) was above the target of 10 and is not of concern. An aggregate assessment was also conducted for incidental oral exposures of children mouthing treated textiles, polymers (plastic toys), and vinyl tiles. The total aggregate MOE for incidental

oral exposure to children (MOE = 69) is below the target MOE of 100 and, therefore is of concern. To mitigate the incidental oral aggregate risks of concern for children, the OIT Task Force has agreed to prohibit the use of OIT preserved plastics to manufacture children's toys. Product labels with this use must be amended to prohibit the use of OIT preserved plastics to manufacture children's toys. By removing the toy scenario, the MOE becomes 128 for the aggregated incidental oral assessment, eliminating aggregate risks of concern for children.

A drinking water assessment was not conducted for OIT because there are no registered outdoor uses for OIT, with the exception of the antisapstain wood preservative use. OIT is stable and persistent in water under abiotic conditions, but shows a tendency to biodegrade in biotic environments. Also, a soil migration study supports that OIT is not expected to be prominent or migrate into water runoff since it binds strongly to the surfaces of soils. OIT does have a tendency to remain on the surface of soils. However, the potential for contamination of surface water, as a result of rainfall, is unlikely to occur because of OIT's tendency to biodegrade in soils and its minimal outdoor uses. Therefore, OIT it is not expected to contact fresh water environments.

The Agency acknowledges that there is a very small chance that the antisapstain use of OIT could potentially result in leaching and runoff when freshly treated wood is stored outdoors. To mitigate the possible risk that antisapstain treated wood, when stored outside, could potentially result in leaching and runoff, precautionary antisapstain label language is required on all antisapstain products. Also, a dietary/drinking water risk assessment was not conducted for the once-through cooling tower use because the registrant has indicated that they will voluntarily cancel this use. In order to be eligible for reregistration, the once-through cooling tower use must be removed from all product labels.

b. Determination of Safety to Infants and Children

The EPA has determined that the currently registered uses of OIT, with 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 susceptibility to the toxic effects of OIT residues in this population subgroup.

No Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from OIT 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 OIT based on: (1) the toxicology database is complete with respect to assessing the increased susceptibility to infants and children as required by FQPA; (2) there is no concern for developmental neurotoxicity resulting from exposure to OIT in the rat and rabbit prenatal developmental studies and the 2-generation reproduction study; (3) there is no evidence of increased susceptibility to the fetus following *in utero* exposure in the prenatal developmental toxicity studies or to the offspring when adults are

exposed in the two-generation reproductive study; and (4) the risk assessment does not underestimate the potential exposure for infants and children.

c. Endocrine Disruptor Effects

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

d. Cumulative Risks

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

D. Regulatory Rationale

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

The following is a summary of the rationale for managing risks associated with the uses of OIT. 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

An acute/chronic dietary risk assessment and an aggregate dietary exposure and risk assessment were not conducted for OIT because the use patterns are not expected to result in acute/chronic dietary exposure and toxicity endpoints were not identified. Therefore, there are no dietary or indirect food contact dietary risks of concern for OIT. No mitigation is needed at this time.

b. Drinking Water Risk Mitigation

There are no registered outdoor uses for OIT, with the exception of the antisapstain wood preservative use. Therefore, the Agency did not conduct a drinking water exposure assessment because OIT is not expected to come into contact with or be exposed to drinking water. Also, a dietary/drinking water assessment was not conducted for the once-through cooling tower use because the registrant has indicated that they will voluntarily cancel this use. In order to be eligible for reregistration, the once-through cooling tower use must be removed from all product labels.

There is a very small chance that the use of OIT for antisapstain wood preservation could potentially result in leaching and runoff when freshly treated wood is stored outdoors. This possible risk can be mitigated with precautionary antisapstain label language. All OIT product labels with the use of antisapstain must be updated to include the appropriate antisapstain label language. Please refer to Table 25 for further information regarding OIT label requirements.

c. Residential Risk Mitigation

i. Handler Risk Mitigation

Residential handler dermal and inhalation risks were assessed for the application of OIT-preserved paint via an airless sprayer and a paint brush/roller. Short-term (ST) inhalation risks of concern were identified for the application of paint via airless sprayer (MOEs = 1-6; target inhalation MOE = 30). The Agency recognizes that the assumptions used in this risk assessment are conservative and believe that actual exposures are significantly less that those generated by the models in this particular case. For instance, the models assume 100% absorption which does not take into account the significant matrix effect that is likely to bind a significant amount of the OIT within the paint matrix making it unavailable for absorption. Evidence is available regarding this matrix effect on dermal availability and more than 70% of the OIT was found to be bound to the paint three hours after exposure. A chamber study is required to further refine the assessment and confirm that a significant matrix effect is also pertinent to the inhalation route of exposure. Further, the study used to derive the toxicological endpoint in the risk assessment had a significant gap (10X) between the dose for the NOAEL and the dose where the effect was seen (LOAEL). It is reasonable to assume that the actual NOAEL may be higher than the level available, based on the dosing range. To better characterize the actual NOAEL the registrants

intend to conduct a new inhalation toxicity study examining doses between the current NOAEL and LOAEL to refine the assessment. Finally, the effect on which this assessment was based, irritation, is not considered to be a severe effect especially when compared to the systemic effects that may be found for other paint preservatives. Based on this rationale, the Agency believes that to address the identified inhalation risks of concern for the application of paint via airless sprayer, the maximum use rate for OIT in paint must be reduced from 0.23% active ingredient to 0.14% active ingredient. Based on the reduced rate and the likelihood that exposure is overestimated based on the rationale presented above, the Agency considered the identified risks to me adequately mitigated and do not pose a risk of concern. The studies described above are necessary to confirm this determination.

ii. Post-Application Risk Mitigation

For the residential post-application assessment, representative scenarios were assessed for short- and intermediate-term incidental oral and dermal exposures to treated carpets (children), treated vinyl (children), and treated mattress covers (children & adults). Post-application scenarios were also assessed for short-term incidental oral exposures of children and dermal exposures of children and adults to treated clothing/textiles. Short-term incidental oral exposures to children mouthing treated plastic toys were also assessed. Post-application inhalation exposures were not assessed because OIT has a relatively low vapour pressure.

Post-application risks of concern were identified for short- and intermediate-term dermal and incidental oral exposures of children to treated carpet (ST dermal MOE = 9; IT dermal MOE = 6; ST incidental oral MOE = 6; IT incidental oral MOE = 13). The OIT Task Force has indicated that OIT is intended to treat carpet-backing only, not carpet fiber. To address theses risks of concern the use of OIT to treat carpet fiber must be cancelled and deleted from all product labels. Also, all product labels must be amended to limit the use of OIT in carpets, to carpet backing only, by adding limitation language to the labels. As a result of the cancellation of the use of OIT to treat carpet fibers, and label language limiting the use of OIT to treat carpet backing only, the Agency has determined that all dermal and incidental oral risks of concern pertaining to children will be eliminated. The rational for this decision is that the Agency does not conduct exposure assessments for treated carpet-backing use scenarios because exposures are unlikely. Therefore, by limiting the use of OIT for carpet to carpet-backing only, dermal and incidental oral exposures to treated carpet fibers will no longer exist. As a result of this mitigation measure, oral and dermal risks of concern will no longer exist for the treated carpet fiber use scenario.

Post-application risks of concern were also identified for intermediate-term dermal exposures of children and adults to treated mattress covers (IT MOE at 5% transfer rate = 73). To mitigate the dermal risks of concern, the application rate of OIT in mattress ticking must be reduced from 0.4% active ingredient to 0.3% active ingredient. Reducing the application rate to 0.3% active ingredient in the mattress ticking scenario changes the intermediate-term dermal exposure to 0.062 mg/kg/day, resulting in an MOE of 96. Although the MOE of 96 is below the Agency target of 100, the Agency believes that this use does not pose as a risk of concern because the risk assessment is based on conservative exposure assumptions and the MOE is very close to the target of 100. Therefore, the Agency believes that there are no dermal risks of

concern to children from exposure to treated mattress ticking, at the reduced application rate of 0.3% active ingredient. All product labels with the mattress ticking use scenario must be amended to reflect the reduced application rate.

For the post-application risk assessment exposures to children and adults from treated clothing and treated mattresses were conducted using a 5% transfer rate. The short-term dermal MOE for exposure of children and adults to treated clothing/textiles is above the target MOE of 10 at a 5% transfer rate (MOE @ 5% transfer rate = 116). The ST dermal MOE for exposure of children and adults to treated mattresses is also above the target MOE of 10 at a 5% transfer rate (MOE @ 5% transfer rate = 110); and the IT dermal MOE for exposure to adults to treated mattresses is above the target MOE of 100 at a 5% transfer rate (MOE @ 5% transfer rate = 110). An Indoor Surface Residue Dissipation study is needed to verify the 5% transfer rate for treated clothing/ textiles and mattresses (GL #875.2300).

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

Inhalation risks of concern were identified without the use of a respirator (PPE) for plastics/vinyl preservation via liquid pour and liquid pump; paint preservation via liquid pour and liquid pump; and textile preservation via liquid pour. To mitigate these inhalation risks of concern, occupational handlers must wear a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE pre-filter. Please refer to Table 25, in this document, for guidance on the PPE label language that is required for occupational use of OIT. The use of a respirator eliminates the inhalation risks of concern by raising the MOEs, assessed without the use of a respirator 10 fold. For plastics and vinyl preservation via liquid pour and liquid pump the MOEs are raised to 20 with the addition of a respirator. Although the MOE of 20 is below the Agency's target MOE of 30, the Agency believes that these uses do not pose as occupational risks of concern with the use of a respirator because the risk assessment is based on conservative exposure assumptions and the MOE is close to the target of 30. Therefore, the Agency believes occupational inhalation risks of concern for the preservation of plastics and vinyl via liquid pour and liquid pump will be mitigated with the use of a respirator. Moreover, receipt of the inhalation toxicity study will allow further refinement of the risk assessment.

Dermal risks of concern were identified for occupational handler intermediate-term exposure resulting from plastic & vinyl preservation via liquid pour (MOE = 39) and liquid pump (MOE = 83); and paint preservation via liquid pour (MOE = 67). Dermal exposures for these industrial applications were assessed wearing gloves, long sleeve shirts, and long pants. These risks can be mitigated with the addition of further personal protective equipment (PPE) by having the handlers wear a face shield and a chemical resistant apron. Currently the Agency does not have method for quantifying the extra protection of an apron and face shield. However, it is believed that the addition of this equipment will eliminate dermal risks of concern for workers. To mitigate the dermal risks of concern for occupational handlers, all product labels for plastic/vinyl preservation via liquid pour and liquid pump, and paint preservation via liquid pour must include the following PPE statement: "Occupational handlers must wear chemical-resistant gloves, face shield, chemical-resistant apron worn over long sleeved shirt and long pants and a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or

HE pre-filter." Please refer to Table 25, in this document, for guidance on the PPE label language that is required for occupational use of OIT.

Inhalation risks of concern were also identified for the application of paint via a brush/roller (ST/IT MOE = 25) and via airless sprayer (ST/IT MOE = 1-2). The Agency recognizes that the assumptions used in this risk assessment are conservative and believe that actual exposures are significantly less that those generated by the models in this particular case. For instance, the models assume 100% absorption which does not take into account the significant matrix effect that is likely to bind a significant amount of the OIT within the paint matrix making it unavailable for absorption. Evidence is available regarding this matrix effect on dermal availability and more than 70% of the OIT was found to be bound to the paint three hours after exposure. A chamber study is required to further refine the assessment and confirm that a significant matrix effect is also pertinent to inhalation route of exposure. Further, the study used to derive the toxicological endpoint in the risk assessment had a significant gapping (10X) between the dose for the NOAEL and the dose where the effect was seen. It is reasonable to assume that the actual NOAEL may be much higher than the level the Agency chose. To better characterize the actual NOAEL the registrants intend to conduct a new inhalation toxicity study examining doses between the current NOAEL and LOAEL to refine the assessment. Finally, the effect on which this assessment was based, irritation, is not considered to be a severe effect especially when compared to the systemic effects that may be found for other paint preservatives. Based on this rationale, the Agency believes that to address the identified inhalation risks of concern for the application of paint via airless sprayer, the maximum use rate for OIT in paint must be reduced from 0.23% active ingredient to 0.14% active ingredient. Based on the reduced rate and the likelihood that exposure is overestimated based on the rationale presented above, the Agency considered the identified risks to me adequately mitigated and do not pose a risk of concern. Receipt of previously identified data are needed to confirm this determination.

An occupational handler exposure assessment was not conducted for the industrial processes and wastewater systems use (water system biocide use). The water system use is only listed on one manufacturing use product (MUP) label (Reg. #707-308), which does not provide application or use rates. Since there are no end-use product (EUP) labels containing water system uses, these uses were not assessed. The industrial process and wastewater treatment use must be deleted from all manufacturing use product labels or new end-use product labels need to be formally submitted and reviewed by the Agency.

ii. Post-Application Risk Mitigation

Occupational post-application exposures are expected to be negligible and, therefore, there are no occupational post-application risks of concern. Mitigation measures are not necessary at this time.

2. Environmental Risk Management

For the industrial processes and wastewater use, the Agency conducted a Tier I "down-the-drain" risk assessment to simulate industrial process wastewater releases. No acute, chronic, or endangered species Level of Concerns (LOCs) were exceeded for aquatic animals and green algae. However, the "down-the-drain" risk assessment is incomplete due to missing non-target plant eco-toxicity endpoints. Plants are the most sensitive species tested. Therefore, plant toxicity data are required to evaluate toxicity to other non-target plant groups and to conduct a complete assessment for the industrial processes and wastewater use pattern. Terrestrial animals are not expected to be exposed to residues greater than those predicted by the "down-the-drain" model.

The registrant has indicated that they will voluntarily cancel the once-through cooling tower use. Therefore, a dietary/drinking water assessment was not conducted for this use. In order to be eligible for reregistration, this use must be removed from all product labels.

The Agency could not conduct an ecological risk assessment for the use of OIT as an antisapstain wood preservative as a result of major data deficiencies. Such data include a soil Koc and wood leaching-rate data, which are required before a Tier I antisapstain environmental risk assessment can be conducted. It is important to note that surface water monitoring data, that can obtain expected environmental concentrations (EECs), may be submitted in lieu of an antisapstain model. The need for chronic fish and aquatic invertebrate data has been triggered due to the high toxicity of OIT to aquatic organisms. However these studies will be held in reserve pending the results of the Tier I antisapstain risk assessment. The identified outstanding plant toxicity studies and ecological toxicity data must be submitted to the Agency in order to conduct the antisapstain wood treatment risk assessment. These data needs are outlined in Chapter V, Table 24.

The following statement must be added to all product labels because the acute toxicity to fish, aquatic invertebrates, and estuarine/marine species are less then 1.0 mg/L:

> This product is toxic to fish, aquatic invertebrates, oysters and shrimp.
> Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Registrants are responsible for amending all OIT antisapstain wood preservative product labels to incorporate the required antisapstain use label language. The following statement must be placed on all antisapstain products to decrease leaching risks:

> Treated lumber must be stored under-cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, steam, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it should consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events.

To address exposure to non-target insects, a special honeybee study is required for all wood preservative uses unless a statement prohibiting the use of treated wood in hive construction is added to the label such as, "Wood treated with OIT shall not be used in the construction of beehives." This study is a combination of Guidelines 171-4 and 850.3030 (see information regarding residue data requirements for uses in beehives in the residue chemistry section of 40 CFR part 158). Numbers of bees used in this study and methods for collection/introduction of bees into hives, feeding, and observations for toxicity and mortality should be consistent with those described in OPPTS Guideline 850.3030, "Honey Bee Toxicity of Residues on Foliage." The toxicity portion of this study is in lieu of the honeybee contact LD50 test.

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 OIT. 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

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 IIB, 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. The active ingredient uses of OIT, with the exception of the industrial waste water discharges and the antisapstain wood preservation uses, fall into this category.

Risks to aquatic animals and green algae were not identified, using Tier I "down-the-drain" modeling to assess potential exposure from industrial waste water discharges. However, the industrial waste water discharges assessment is considered to be incomplete due to missing non-target plant eco-toxicity endpoints. The full compliment of plant toxicity tests are required to confirm that green algae is the most sensitive non-target plant species. Terrestrial animals are not expected to be exposed to residues greater than those predicted by the "down-the-drain" model. A No Effect determination is made for terrestrial and aquatic animal species from "indoor" OIT uses. However, the Agency defers making an endangered species determination for terrestrial and aquatic plants from "indoor" uses (industrial waste water treatment use) of OIT until after receipt of outstanding data.

A Tier I antisapstain risk assessment model could not be conducted to assess potential exposure from treated antisapstain wood products due to the lack of OIT wood leaching-rate data and soil Koc's. An environmental monitoring study of run-off from antisapstain treatment facilities is suggested to address the potential risks and to provide EECs for a risk assessment as an alternative to an antisapstain Tier I assessment. Impacts from the antisapstain use could potentially be mitigated with precautions to prevent leaching and run-off when wood is stored outdoors (see General Risk Mitigation, below). Due to these circumstances, the Agency defers making a determination for the antisapstain uses of OIT until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the antisapstain use of OIT will be revised, and the risks to Listed Species will be reconsidered.

b. General Risk Mitigation

OIT end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing OIT specific to federally listed species, the Agency needs to address potential risks from other end-use products.

Therefore, the Agency requires that users adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need to Do

The Agency has determined that OIT is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; (ii) the risk mitigation measure outlined in this document is adopted; and (iii) label amendments are made to reflect this measure. To implement the risk mitigation measure, the registrants must amend their product labeling to incorporate the label statement set forth in the Label Changes Summary Table in Section B below (Table 24). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For OIT 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 K. Avivah Jakob at (703) 305-1328 with questions regarding generic reregistration.

By US mail:

Document Processing Desk
K. Avivah Jakob
Office of Pesticide Programs
(7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:

Document Processing Desk
K. Avivah Jakob
Office of Pesticide Programs
(7510P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

For end-use products containing the active ingredient OIT, 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 23 of this document;

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

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

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

Please contact Marshall Swindell at (703) 308-6341 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
Marshal Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:

Document Processing Desk
Marshal Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

Residential & Occupational Handler Confirmatory Data

A 21/28-day dermal toxicity study (870.3200) is needed to refine the dermal exposure estimates for both the residential and occupational painter scenarios. The dermal exposure estimate for both the residential and occupational painter scenarios, using treated paint, was based on wet film thickness data from a study where the user's hands were immersed twice in mineral oil. No information specific to the wet film thickness of paint was identified. The method employed may result in an underestimate of dermal exposures to paint. Therefore, this assessment could be refined by conducting a dermal irritation study where OIT treated paint is the test substance.

An inhalation exposure study (chamber study) (875.2500) is needed to further refine the residential and occupational handler assessments and to confirm that a significant matrix effect is also pertinent to the inhalation route of exposure. The Agency recognizes that the assumptions used in the OIT risk assessment are conservative and believe that actual exposures are significantly less that those generated by the models in this particular case. For instance, the models assume 100% absorption which does not take into account the significant matrix effect that is likely to bind a significant amount of the OIT within the paint matrix making it unavailable for absorption. Evidence is available regarding this matrix effect on dermal availability and more than 70% of the OIT was found to be bound to the paint three hours after exposure. Therefore, an inhalation exposure study is needed to further refine the assessment.

A 90-day inhalation toxicity study (870.3465) is needed to better characterize the inhalation NOAEL and to refine the residential and occupational exposure assessments. The study used to derive the toxicological endpoint in the risk assessment had a significant gap (10X) between the dose for the NOAEL and the dose where the effect was seen. It is reasonable to assume that the actual NOAEL may be much higher than the level the Agency chose. To better characterize the actual NOAEL the registrants intend to conduct a new inhalation toxicity study examining doses between the current NOAEL and LOAEL to refine the assessment.

Surrogate dermal and inhalation unit exposure values were taken from the proprietary CMA antimicrobial exposure study (USE EPA 1999: DP Barcode D247642). Most of the CMA data are of poor quality and, therefore, the Agency requests that confirmatory monitoring data be generated to support the values used in the occupational and residential risk assessments and to further refine these assessments. The following confirmatory monitoring data are needed: dermal exposure-indoor & outdoor data (875.1200 & 875.1100, respectively), and inhalation exposure-

indoor & outdoor data (875.1400 & 875.1300, respectively). Product use information (875.1700) and description of human activity data (875.2800) are also needed to further define the exposure scenarios being supported and to further refine the assessments.

Residential Post-Application Confirmatory Data

An indoor surface residue dissipation study (GL 875.2300) is needed to verify the 5% transfer rate from treated clothing/textiles and from treated mattresses.

Environmental Fate and Ecological Exposure Confirmatory Data

Non-target plant toxicity data are needed to further refine and complete the "down-the-drain" risk assessment for the industrial process and wastewater releases. For the industrial processes and wastewater use, the Agency conducted a Tier I "down-the-drain" risk assessment to simulate industrial process wastewater releases. However, the "down-the-drain" risk assessment is incomplete due to missing non-target plant eco-toxicity endpoints. Plants are the most sensitive species tested. Therefore, plant toxicity data are required to evaluate toxicity to other non-target plant groups and to conduct a complete assessment for the industrial processes and wastewater use pattern.

The OIT Task Force has identified that they wish to cancel the once-through cooling tower use. However, receipt of this removal has not yet been submitted. Unless the registrant formally cancels this use, the data requirements for the once-through-cooling tower use will be applicable.

The Agency could not conduct an ecological risk assessment for the use of OIT as an antisapstain wood preservative as a result of major data deficiencies. Such data include a soil Koc and wood leaching-rate data, which are required to conduct a Tier I antisapstain environmental risk assessment. It is important to note that surface water monitoring data, that can obtain expected environmental concentrations (EECs), may be submitted in lieu of an antisapstain model. The need for chronic fish and aquatic invertebrate data has been triggered due to the high toxicity of OIT to aquatic organisms. However these studies will be held in reserve pending the results of the Tier I antisapstain risk assessment. The identified outstanding plant toxicity studies and ecological toxicity data must be submitted to the Agency in order to conduct the antisapstain wood treatment risk assessment.

Table 24, below, provides an outline of the requested human health and ecological confirmatory data needs for OIT.

Table #24. Data Requirements for OIT

Guideline Study Name	New OPPTS Guideline Number
Human Health Confirmatory Data	
21/28-Day dermal Toxicity Study	870.3200
Inhalation Exposure Study	875.2500
90-Day Inhalation Toxicity Study	870.3465
Indoor Surface Residue Dissipation Study	875.2300
Dermal exposure-indoor & outdoor data	875.1200 & 875.1100
Inhalation exposure-indoor & outdoor data	875.1400 & 875.1300
Product Use Information	875.1700 & 875.2700
Description of Human Activity Data	875.2800
Environmental Fate & Ecological Exposure Confirmatory Data	
Freshwater Diatom	850.5400
Blue-green Cyanobacteria	850.5400
Marine Diatom	850.5400
Freshwater Floating Macrophyte Duckweed	850.4225
Freshwater Rooted Macrophyte Rice Seedling Emergence	850.4225
Freshwater Rooted Macrophyte Rice Vegetative Vigor	850.4250
Soil Koc Study	835.1220
Wood Leaching Study	AWPA Method E11-06, Standard Method of Determining the Leachability of Wood Preservatives Immersed in Water, AWPA, 2006
Residues in honey/beeswax and toxicity of treated wood residues to bees *(This test can be waived provided that labels are amended as outlined for wood preservative use)*	Combination of Guideline 860.1500 and 850.3030

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 25, 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 will be issued at a later date.

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 25, Label Changes Summary Table.

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, all product labels must be amended to incorporate the risk mitigation measure outlined in Section IV of the OIT RED. The following table describes how language on the labels should be amended.

Table 25. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Occupational Use		
PPE Requirements	"Wear chemical-resistant gloves, goggles, face shield, chemical-resistant apron worn over long sleeved shirt and long pants and a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE pre-filter"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
For all antisapstain end-use products	"Antisapstain treated lumber must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, steam, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it should consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events."	This language is to be included in the Environmental Hazards section of the label.
Directions For Use		
End Use Products Intended for Plastic Preservation (or treated plastic products)	"Treated plastics can not be used to manufacture children's toys"	
End Use Products Intended for Carpet Treatment	"Use only to treat carpet-backing. Not for use in carpet fibers."	

VI. APPENDICES

Appendix A. Table of Use Patterns for OIT

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Materials preservatives				
Coatings: latex and solvent-based paints, semi-transparent stains and solid stains.	707-100 (Formulation Intermediate)	Incorporated into formulation of end use product	1.0 to 4.0 pounds of product per 100 gallons of coating formulation.	None Listed
	707-208 (Soluble Concentrate)	Incorporated into formulation of end use product	1.64 to 6.55 pounds of product per 100 gallons of coating formulation.	None Listed
	707-303 (Soluble Concentrate)	Incorporated into formulation of end use product	0.25 to 2.0 pounds of product per 100 gallons of coating formulation.	None Listed
Paints and Coating Materials	5383-101 5383-102 (Ready to Use)	Added at the beginning of the formulation process while mixing of the final product.	(0.2-2.0%) add 2-20 lbs. (0.9-9.0kg) of product to each 1000 lbs. (453 kg.) of paint.	None Listed
	67071-6 (Ready to Use)	Incorporated into formulation of end use product	0.1 to 5 pounds of product per 100 gallons of paint.	None Listed
	67071-17 (Emulsifiable Concentrate) 67071-39 (Soluble Concentrate)	Not listed	0.20 to 2.5% (wt/wt) based on paint or coating used on the surface.	Not for incorporation in products used to paint swimming pools.
	67071-31 (Soluble Concentrate)	Incorporated with products during the manufacturing process	Add 0.1% to 2.0% of product based on weight of the formulation of paint or wood coating.	None Listed

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Plasters & Stuccos	5383-101 5383-102 (Ready to Use)	Added at the beginning of the formulation process while mixing of the final product.	((0.1 – 1.0) add 1 – 10lbs. (0.45 – 4.5kg) of product to each 1000 lbs. (453 kg.) of plasters.	None Listed
Sealants, caulks and fillers	5383-101 5383-102 (Ready to Use)	Added at the beginning of the formulation process while mixing of the final product.	(0.1 – 1.5%) add 1 – 15 lbs. (0.45 – 6.8kg.) of paste to each 1000 lbs. (453 kg.) of sealant filler.	None Listed
	67071-17 (Emulsifiable Concentrate)	Not listed	0.20 to 0.75% (wt/wt) based on formulations For higher humidity areas: up to 2.5% product may be required	None Listed
Concentrates	707-100 (Formulation Intermediate)	Incorporated into formulation of end use product	1.0 to 3.0 pounds of product per 100 gallons of coating formulation.	None Listed
Building Materials: elastomeric roof, wall coatings, mastics, caulks, sealants, joint cements, spackling, stucco and grouting	707-100 (Formulation Intermediate)	Incorporated into formulation of end use product	1.0 to 3.0 pounds of product per 100 gallons of coating formulation.	None Listed
	707-208 (Soluble Concentrate)	Incorporated into formulation of end use product	5.9 to 8.2 pounds of product per 100 gallons of coating formulation.	None Listed
	707-303 (Soluble Concentrate)	Incorporated into formulation of end use product	0.25 to 3.0 pounds of product per 100 gallons of coating formulation.	None Listed
Wallpaper Pastes and Adhesives	707-100 (Formulation Intermediate)	Incorporated into formulation of end use product	0.1 to 415 pounds of product per 100 gallons of coating formulation.	None Listed
	707-208 (Soluble Concentrate)	Incorporated into formulation of end use product	0.12 to 0.16 pounds of product per 100 gallons of coating formulation.	None Listed

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Aqueous Adhesive and Tackifier Preservation	707-100 (Formulation Intermediate)	Incorporated into formulation of end use product	1.0 to 0.20 pounds of product per 100 gallons of coating formulation.	None Listed
	707-208 (Soluble Concentrate)	Incorporated into formulation of end use product	0.05 pounds of product per 100 gallons of coating formulation.	None Listed
	3090-217 (Soluble Concentrate)	Not Listed	Use a concentration of 0.3 to 1.5 of product relative to the total weight of the material being treated.	None Listed
	67071-6 (Ready to Use)	Incorporated into formulation of end use product	0.1 to 5 pounds of product per 1000 gallons of adhesive.	None Listed
Water based Emulsions/ Adhesives	10466-42 (Soluble Concentrate)	Add as a component to final product prior to mixing	Apply 0.8 to 1.5% of product by weight.	None Listed
Fabric Mildewcide	707-121 (Ready to Use)	Add to final rinse of fabric	1.14 to 2.28 fluid ounces of product for every 100 gallons of final rinse. 0.68 to 1.37 fluid ounces of product for every 100 pounds of fabric treated	None Listed
	707-208 (Soluble Concentrate)	Add to final rinse of fabric	0.27 fluid ounces of product for every 100 gallons of final rinse. 0.68 to 0.114 fluid ounces of product for every 100 pounds of fabric treated.	None Listed
	707-236 (Ready to Use)	Add to final rinse of fabric	1 ¼ to 2 1/2 fluid ounces of product for every 100 gallons of final rinse.(5-10ppm active ingredient)	None Listed

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Fabric Mildewcide			3/4 to 1 1/2 fluid ounces of product for every 100 pounds of fabric treated (3-6ppm active ingredient)	
	67071-6 (Ready to Use)	Not Listed	0.1 to 0.25% by weight of product calculated on the materials weight.	None Listed
Fabrics w/ Human Contact: Mattress Ticking, footwear fabrics, outerwear, hosiery, Feathers and Down	3090-217 10466-42 (Soluble Concentrate)	Not Listed Add to the cold liquor at room temperature, run for 5 minutes cold then raise temperature to 49C/120F over a period of 15 minutes, Maintain bath at the stated temperature for a further 15 minutes.	Use a concentration of 1.0 to 2.0% of product relative to the dry weight of the fabric/textile/material being treated	None Listed
Latices: (Polymers, synthetic, Rubber)	3090-217 (Soluble Concentrate)	Not listed	Use a concentration of 0.3 to 1.5% of the product relative to the total weight of the material being treated.	None Listed
Leather Preservative	707-121 (Ready to Use)	Incorporated in tanning process	1170ppm to 3530ppm to every 10,000 pounds of wet hide.	None Listed
	707-236 (Ready to Use)	Incorporated in tanning process	1260ppm to 3780ppm to every 10,000 pounds of wet hide.	None Listed
	1448-412 (Soluble Concentrate)	Incorporated in tanning process	0.01-0.3% (100 – 10,000ppm)	None Listed

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	67071-6 (Ready to Use)	Not listed	0.014 to 0.045% of product calculated on the pelt weight.	None Listed
	39967-46 (Soluble Concentrate)	Gradually add to float or to product to be preserved	0.2-0.5% product calculated on the pelt weight	None Listed
Chrome	39967-46 (Soluble Concentrate)	Gradually add to float or to product to be preserved	Dilute with 2-5 parts water.	None Listed
Metalworking Fluid Preservation	707-195 67071-6 (Ready to Use)	Dispensed directly into metalworking concentrate	55 to 167 ppm of product/ 25 to 75 ppm of active ingredient for final use dilution initial dose 0.47 to 1.44 pounds (7 to 21 fluid ounces) of product per 1000 gallons of emulsion 25-75ppm of active ingredient. Subsequent Dose: 0.09 to 0.58 pounds (1.3 to 8.6 fluid ounces) of product per 1000 gallons of emulsion every 4 weeks. Provides 5 to 30 ppm active ingredient.	None Listed
Hydraulic Fluid Preservation	67071-6 (Ready to Use)	Dispense directly into the hydraulic concentrate using a metered pump	55 to 167 ppm of product/ 25 to 75 ppm of active ingredient for final use dilution initial dose 0.47 to 1.44 pounds (7 to 21 fluid ounces) of product per 1000 gallons of emulsion 25-75ppm of active ingredient. Subsequent Dose: 0.09 to 0.58 pounds (1.3 to 8.6 fluid ounces)	None Listed

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			of product per 1000 gallons of emulsion every 4 weeks. Provides 5 to 30 ppm active ingredient.	
Polymer Compounds	707-208 (Soluble Concentrate)	Incorporated into formulation of end use product	0.15 to 0.36 pounds of product per 100 pounds of compounded polymer systems.	None Listed
	10466-42 (Soluble Concentrate)	Add product in post treatment	Apply 0.8 to 1.5% of product by weight.	None Listed
Polymer Latex Preservation	707-286 (Soluble Concentrate)	Add latex	2.15 to 4.29 pounds of product (971 – 1946 grams) to each 1000 pounds (453 kilograms) of fluid to provide 2143 – 4290 ppm product 9500 – 1000ppm active ingredient)	Finished textile articles incorporating this product may not make any pesticidal claims without obtaining a pesticide registration. Consult PR Notice 2000 for allowable claims for treated articles.
Vinyl: shower Curtains, wall coverings, mattress covers, interior automotive parts, coated fabrics for upholstery.	2829-127 (Ready to Use)	Incorporated into formulation of end use product	3% of product based on total weight of formulation of items for interior use. 5% of product based on total formulation of items subjected to extended outdoor weathering.	None Listed
Exterior use Vinyl: landau tops, exterior automotive trim, tarpaulins, awnings, ditch and pond liners, marine upholstery, swimming pool liners.	2829-133 (Pelleted Tableted)	Incorporated into formulation of end use product	1.2% of product based on total weight of formulation of items for interior use. 2.0% of product based on total formulation of items subjected to extended outdoor weathering.	None Listed
	5383-128	Incorporated into formulation during mixing or compounding process	Suggested concentrations between 2 and 5%	Product should not be used in treated articles which are intended to contact food or drinking water.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	67071-43 (Soluble Concentrate)		Add 0.5% to 4.0% of product based on the total weight of the formulation/ composition.	None Listed
Casein/Resin	3090-217 (Soluble Concentrate)	Not Listed	Use a concentration of 0.3 to 1.5% of the product relative t the total weight of the material being treated.	None Listed
Plasticized PVC Exterior items: swimming pool liner, roof liner, lining foils, cable casings, tarpaulins, tents, garden hoses, Interior Items: Floor and wall coverings, coated furniture fabrics, shower curtains, awnings.	3090-219 (Soluble Concentrate)	Incorporated at various stages of manufacturing process	Finished product to contain 0.5 to 1.4% by weight of the additive	Product is not registered for use as a sanitizer Do not use in the manufacture or treatment of items that may come in contact with food. Do not use for the production of baby diapers or fibers for the production of baby diapers. Do not use for the production of health care products or products intended to decrease the transmission of disease (items regulated by the FDA)
	67071-6 (Ready to Use)	Can be introduced in different phases of the process cycle.	Interior products: 0.1 to 0.5% of product based on total weight of the formulation/composition. Exterior products: 0.15% to 0.75% of product based on the total weight of the formulation/ composition.	Product should never be introduced directly into fillers and pigments.
Plasticized PVC Exterior items: swimming pool liner, roof liner, lining foils, cable casings, tarpaulins, tents, garden hoses, Interior Items: Floor and wall coverings, coated furniture fabrics, shower curtains, awnings.	81348-8 (Soluble Concentrate)	Not listed	Interior: Level of 1.2% product based on total weight of the final treated product. Exterior products: a level of 2% should be evaluated	Do not use product where treated plastic materials can come into contact with humans or pets or be used as food or feed packing materials or as food contact surfaces.
Human Clothing PVC Items: Rain wear, protective wear, shoes, boots, PVC slippers,	3090-219 (Soluble Concentrate)	Incorporated at various stages of manufacturing	Finished product to contain 0.5 to 1.4% by weight of the additive	Product is not registered for use as a sanitizer.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
gloves.		process		
Industrial Processes and Water Systems				
Air Washer Water	707-308 (Formulation Intermediate)	Not Stated	Not Stated	None Stated
Cooling Tower Water	707-308 (Formulation Intermediate)	Not Stated	Not Stated	None Stated
Antifouling Coating				
Boats/ Ships: Wood, fiberglass or metal	48302-12 (Ready to Use)	Spray, brush or Roll on	192 sq. ft/gal at 4.0 mils or 960 sq. ft. per container	Do not apply by airless spray. Do not apply more than one coat of product within 24 hours. Apply only in outdoor, non-enclosed spaces. Do not launch vessels before recommended drying time.
Wood Preservation				
Debarked logs to be made into plywood	73612-1 (Soluble Concentrate)	Spray	40 to 180 liters of product concentrate per 1,000 liters of water.	Treated Wood Must not be used where it may contact food or animal feed.

Appendix B: Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide to Appendix B

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Octhilinone. These requirements apply to Octhilinone 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 establishment 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 identify 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.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) CHEMISTRY				
830.1550	61-1	Product Identity and Composition	7, 8, 9, 10	43499601
830.1600 830.1620 830.1650	61-2A	Starting Materials and Manufacturing Process	7, 8, 9, 10	43499601
830.1670	61-2B	Formation of Impurities	7, 8, 9, 10	43499601
830.1700	62-1	Preliminary Analyses	7, 8, 9, 10	43505501
830.1750	62-2	Certification of Limits	7, 8, 9, 10	43499601, 43505501
830.6302	63-2	Color	7, 8, 9, 10	43499602
830.6303	63-3	Physical state	7, 8, 9, 10	43499602
830.6304	63-4	Odor	7, 8, 9, 10	43499602
830.7220	63-6	Boiling Point	7, 8, 9, 10	43499603, 43499602
830.7300	63-7	Density	7, 8, 9, 10	43499605, 43499602
830.7840 830.7860	63-8	Solubility	7, 8, 9, 10	43499606, 43499602

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7950	63-9	Vapor Pressure	7, 8, 9, 10	41222604, 41482501, 43499607, 43499602
830.7370	63-10	Dissociation Constant	7, 8, 9, 10	43499608, 43499602
830.7550/830.7570	63-11	Partition coefficient (*n*-octanol/water), shake flask method/Partition coefficient (*n*-octanol/water), estimation by liquid chromatography	7, 8, 9, 10	43499609, 43499602
830.7000	63-12	pH	7, 8, 9, 10	43499602
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	7, 8, 9, 10	43499610, 43499602
830.6317	63-17	Storage Stability	7, 8, 9, 10	43499611, 43499602
830.7100	63-18	Viscosity	7, 8, 9, 10	43499602
830.6320	63-20	Corrosion characteristics	7, 8, 9, 10	43499602
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian acute oral toxicity test – Quail/Duck	7, 8, 9, 10	00026809, 41608002, 41608003, 44859001
850.2200	71-2	Avian dietary toxicity test – Duck/Quail	7, 8, 9, 10	00026807, 00026808, 41608001, 43935701

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1075	72-1	Fish acute toxicity test – Freshwater - Bluegill/Rainbow trout/Daphnia magna/Oncorhynchus mykiss/Leopomis macrochirus	7, 8, 9, 10	41608004, 41608005, 41608006, 43935702, 43935703
850.1010	72-2	Aquatic invertebrate acute toxicity test, freshwater daphnids	7, 8, 9, 10	43935704
850.1025	72-3	Oyster acute toxicity test (shell disposition)	7, 8, 9, 10	41700701
850.1035	72-3	Mysid acute toxicity test	7, 8, 9, 10	41608008
850.1075	72-3	Fish acute toxicity test – Estuarine/Marine	7, 8, 9, 10	41608007
850.1085	72-4	Fish acute toxicity mitigated by humic acid	7, 8, 9, 10	00026805, 41909301
850.1300	72-4	Daphnid chronic toxicity test	7, 8, 9, 10	41909401, 43935704
850.5400	123-2	**Algal toxicity, Tiers I and II**		
		Green algae – *Selenastrum capricornutum* (*Pseudokerscheneria subcapitatum*)	7, 8, 9, 10	44071001
		Blue-green cyanobacteria – *Anabaena flos-aquae*		Data Gap
		Freshwater diatom – *Navicula pelliculosa*		Data Gap
		Marine diatom – *Skeletonema costatum*		Data Gap
Non-Guideline	Non-Guideline	Acute toxicity to water flea (Daphnia magna)	7, 8, 9, 10	00026806
Non-Guideline	Non-Guideline	Acute toxicological evaluations with wildlife	7, 8, 9, 10	47107013

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
		TOXICOLOGY		
870.1100	81-1	Acute oral toxicity - Rat	7, 8, 9, 10	00063214, 00070456
870.1200	81-2	Acute dermal toxicity – Rabbit	7, 8, 9, 10	00070456
870.1300	81-3	Acute inhalation toxicity – Rat	7, 8, 9, 10	00063214
870.2400	81-4	Acute eye irritation – Rabbit	7, 8, 9, 10	00063214
870.2500	81-5	Acute dermal irritation	7, 8, 9, 10	00063214
870.2600	81-6	Skin sensitization	7, 8, 9, 10	00063214, 41482505, 41482507,
870.3100	82-1	90-Day oral toxicity in rodents	7, 8, 9, 10	00136524
870.3150	81-2	90-Day oral toxicity in nonrodents	7, 8, 9, 10	00136525
870.3200	82-2	21/28-Day dermal toxicity	7, 8, 9, 10	00136526
870.3250	82-3	90-Day dermal toxicity	7, 8, 9, 10	42007301, 43935705, 43935706
870.3465	82-4	90-Day inhalation toxicity	7, 8, 9, 10	00136527, 41544701

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.4200	83-2	Carcinogenicity	7, 8, 9, 10	00139417, 00139419, 00139484
870.3700	83-3	Prenatal developmental toxicity study	7, 8, 9, 10	00046403, 00058029, 00136528, 41482508, 41482509, 43935707, 43944401
870.5100	84-2	Bacterial reverse mutation test	7, 8, 9, 10	43935708
870.5195	84-2	Mouse biochemical specific locus test	7, 8, 9, 10	43935709
870.5550	84-2	Unscheduled DNA synthesis in mammalian cells in culture	7, 8, 9, 10	40647505
870.5385	84-2	Mammalian erythrocyte micronucleus test	7, 8, 9, 10	43935710
Non-Guideline	Non-Guideline	Contact Dermatitis	7, 8, 9, 10	Open Literature
ENVIRONMENTAL FATE				
835.2110	161-1	Hydrolysis as a function of pH	7, 8, 9, 10	44723201

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, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained the May 25, 2007 preliminary risk assessment and the related documents. EPA then considered comments on these risk assessments (which are posted to the e-docket) and revised the risk assessments. The revised risk assessments will be posted in the docket at the same time as the RED.

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

These documents include:

Reregistration Eligibility Decision (RED) Document:

- Reregistration Eligibility Decision for 2-Octyl-3 (2H)-isothiazolone (OIT), 09/28/2007

Preliminary Risk Assessment and Supporting Science Documents:

- Revised Octhilinone Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 099901 (active). Case No. 2475. DP Barcode: D337742, 5/25/2007
- Revised Occupational and Residential Exposure Chapter for Octhilinone (OIT) for Reregistration Eligibility Decision (RED0 Document (Case 2475), 5/25/2007
- Transmittal of Octhilinone (OIT) RED Ecological Hazard and Environmental Risk Assessment Chapter-Case Number 2475, 3/7/2007
- Environmental Fate Assessment of Octhilinone, 3/30/2007
- Incident Reports Associated with Octhilinone, 4/5/2007
- Product Chemistry of Octhilinone for Reregistration Eligibility Decision (RED), 2/6/2007
- Dietary Exposure Assessment of Octhilinone Use of Indirect Food Contact Surfaces, 2/21/2007
- Evaluation of Toxicology Database for the Reregistration Eligibility Decision Document Disciplinary Chapter, 3/5/2007

Revised Risk Assessment and Supporting Science Documents:

- Revised Octhilinone Risk Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 099901 (active). Case No. 2475. DP Barcode: D337742, 9/20/2007
- Evaluation of Toxicology Database for the Reregistration Eligibility Decision Document Disciplinary Chapter, 10/31/2007
- Revised Occupational and Residential Exposure Chapter for Octhilinone (OIT) for the Reregistration Eligibility Decision (RED) Document (Case 2475), 9/17/2007

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

1. MRID Studies

MRID#	Citation
00010890	Copley, M. (1994) Octhilinone Waiver Request for a Dermal of Sensitization Study; Unpublished study prepared by the U.S. EPA, ID 099901-000707, Apr. 8, 1994.
00026805	Hutchinson, C. (1979) Bioassay Report: Acute Toxicity of RH-893 Technical to Five Species of Freshwater Fishes. Unpublished data. Conducted by Bionomics, Inc. for Rohm and Haas Company.
00026806	Stiefel, C. (1979) Acute Toxicity of RH-893 Technical to the Water Flea (Daphnia magna). Lab Report No. BW-79-7-503. Unpublished data. Conducted by Bionomics, Inc. for Rohm and Haas Company.
00026807	Beavers, J.B. et. al. (1979) Eight-day Dietary LC_{50} – Mallard Duck RH-893 Technical (79P-251) Final Report. Unpublished data. Conducted by Wildlife International. Ltd. for Rohm and Haas Company.
00026808	Beavers, J.B. et. al. (1979) Eight-day Dietary LC_{50} – Bobwhite Quail RH-893 Technical (79P-253) Final Report. Unpublished data. Conducted by Wildlife International. Ltd. for Rohm and Haas Company.
00026809	Beavers, J.B. et. al. (1979) Acute Oral LD_{50} – Bobwhite Quail RH-893 Technical (79P-252) Final Report. Unpublished data. Conducted by Wildlife International. Ltd. for Rohm and Haas Company.
00046403	Powers, M.B. (1971) Final Report: Teratology Study-Rats: Project No. 417-349. (Unpublished study received May 25, 1971 under unknown admin. no.; prepared by Hazleton Laboratories, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:107967-A).
00058029	Powers, M.B. (1970) Final Report: Teratology Study-Rabbits: Project No. 417-346. (Unpublished study received Feb 3, 1977 under 984-67; prepared by Hazleton Laboratories, Inc., submitted

by Whitmoyer Laboratories, Inc., Myerstown, Pa.; CDL:229345-A).

00063214 Powers, M.B. (1970) Final Report [for Octhininone]: Acute Oral - Rats; Draize Eye Irritation - Rabbits; Primary Skin Irritation - Rabbits; Skin Sensitization - Guinea Pigs; Acute Inhalation Exposure - Rats: Projects No. 417-323, No. 417-324, No. 417-325, and No. 417-326, 417-327. (Unpublished study, received Jul 18, 1978 under 707-127; prepared by Hazleton Laboratories, Inc., Philadelphia, Pa.; CDL: 234400-C).

00070456 Powers, M.B. (1970) Final Report [for Octhininone]: Acute Oral - Rats; Acute Dermal - Rabbits; Acute Eye Irritation - Rabbits; Acute Inhalation Exposure - Rats: Projects No. 417-306, No. 417-307, No. 417-308, and No. 417-310 and 417-310. (Unpublished study, received April 4, 1978 under 707-143 prepared by TRW, Inc. submitted by Rohm & Haas Co., Philadelphia, Pa; CDL:233428-B).

00136524 Powers, M.; Kundzin, M.; Ferrell, J. (1970) Three-month Dietary Ad- ministration-Rats: RH-893 (Technical): Project No. 417-320. Final report (Unpublished study received Feb 9, 1971 under 707-100; prepared by Hazleton Laboratories, Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL:004372-H).

00136525 Powers, M.; Ferrell, J. (1970) Three-month Dietary Administration- Dogs: RH-893 (Technical): Project No. 417-334. Final report (Unpublished study received Feb 9, 1971 under 707-100; prepared by Hazleton Laboratories, Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL:004372-I).

00136527 Hiddemen, J.; Ferrell, J. (1971) Subacute Inhalation Study-Rats: RH-893-50%: Project No. 417-345. Final report (Unpublished study received Feb 9, 1971 under 707-100; prepared by Hazleton Laboratories, Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL:004372-K).

00136528 Powers, M. (1970) Teratology Study: Rabbits: RH-893 (Technical): Project No. 417-346. Final report (Unpublished study received Feb 9, 1971 under 707-100; prepared by Hazleton Laboratories, Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL: 004372-L).

00139417 Piccirillo, V.J.; Smith, J.M.; Larson, P.S.; et al. (1975) Eighteen Month Study on the Carcinogenic Potential of RH-893 in Mice.

(Unpublished study received Jun 4, 1975 under 5F1632; prepared by Medical College of Virginia, Health Sciences Center, Dept. of Pharmacology and Medical Univ. of South Carolina, Dept. of Pathology, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 094944-B).

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00139484 Piccirillo, V.J.; Smith, J.M. (1975) Eighteen Month Study on the Carcinogenic Potential of RH-893 in Mice. (Unpublished study received Feb 3, 1977 under 984-67; prepared by Medical College of Virginia, Toxicology Research Dept., submitted by Whitmoyer Laboratories, Inc., Myerstown, Pa.; CDL:229346-A).

40647505 Muller, G. (1986) Skane M-8 HQ Microbiocide in vitro Unscheduled DNA Synthesis Assay: Report 86R-0018. Unpublished study prepared by Rohm and Haas Co. 29 p.

41222604 Lorence, PJ, and Walls, GE, (1989) Vapor Pressure Determination of RH-5287, , Rohm and Hass Company, Research Laboratories 727 Norristown Road, Spring House, PA: 19477, Report #: 34-89-23

41482501 Lorence, PJ and Walls, GE, (1989) Vapor Pressure Determination of RH-293. Rohm and Hass Company, Research Laboratories, 727 Norristown, Spring House, PA: 19477, Report #: 34-98-24.

41482505 Murphy, M. Chen, P. (1983) RH-893-A Study of the Concentrated Dependent Delayed Contact Hypersensitivity study in Guinea Pigs; Lab Project Number: 83R-143. Unpublished study prepared by Rohm and Haas Co. 48 p.

41482507 Bonin, R; Murphy, M. (1983) RH-893 Process Variation A Study of the Concentrated-Dependent Delayed Contact Hypersensitivity study in Guinea Pigs; Lab Project Number: 83R-025. Unpublished study prepared by Rohm and Haas Co. 36 p.

41482508 Powers, M. (1970) Teratology Study: Rabbits: RH-893 (Technical): Project No. 417-346. Final report (Unpublished study received Feb 9, 1971 under 707-100; prepared by Hazleton Laboratories, Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL: 004372-L).

41482509 Solomon, H.; Lutz, M. (1987) Skane M-8 HQ Industrial Mildewcide: Oral (Gavage) Developmental Toxicity Study in Rabbits: Lab Project Number: 87R-019: 86P-504. Unpublished study prepared by Rohm and Haas Co. 178 p.

41544701 Hagan, J.; Kulwich, B.; Fisher, J. (1989) Skane M-8 HQ Microbicide: Thirteen-Week Inhalation Toxicity Study in Rats: Protocol No. 86P-196: Report No. 87R-013: Lab Project Number: 87R-013: 86P- 196. Unpublished study prepared by Rohm and Haas Co. 521 p.

41608001 Pedersen, C.A.. (1990) Octhilinone – 21-Day Acute Oral LD50 Study in Bobwhite Quail. Rohm and Haas Report No. 90RC-0020. Unpublished data. Conducted by Bio-Life Associates, Ltd. for Rohm and Haas Company.

41608002 Pedersen, C.A.. (1990) Octhilinone – 8-Day Acute Dietary LC50 Study in Bobwhite Quail. Rohm and Haas Report No. 90RC-0021. Unpublished data. Conducted by Bio-Life Associates, Ltd. for Rohm and Haas Company.

41608003 Pedersen, C.A.. (1990) Octhilinone – 8-Day Acute Dietary LC50 Study in Mallard Ducklings. Rohm and Haas Report No. 90RC-0022. Unpublished data. Conducted by Bio-Life Associates, Ltd. for Rohm and Haas Company.

41608004 Sousa, J.V. (1990) Octhilinone – Acute Toxicity to Bluegill (Lepomis macrochirus) Under Flow-Through Conditions. Lab Report No. 90-7-3375. Unpublished data. Conducted by Springborn Laboratories for Rohm and Haas Company.

41608005 Sousa, J.V. (1990) Octhilinone – Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss) Under Flow-Through Conditions. Lab Report No. 90-7-3367. Unpublished data. Conducted by Springborn Laboratories for Rohm and Haas Company.

41608006 McNamara, P.C. (1990) Octhilinone – Acute Toxicity to Daphnids (Daphnia magna) During a 48-Hour Flow-Through Exposure. Lab

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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 OIT 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 OIT Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching for OIT at a later date.

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: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner

encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

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

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