

US EPA ARCHIVE DOCUMENT



United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-08-002
March 2008

Reregistration Eligibility Decision for Diiodomethyl p-tolyl sulfone

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 diiodomethyl p-tolyl sulfone. The enclosed Reregistration Eligibility Decision (RED) document was approved on March 31, 2008.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone are available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2007-1151 at: www.regulations.gov.

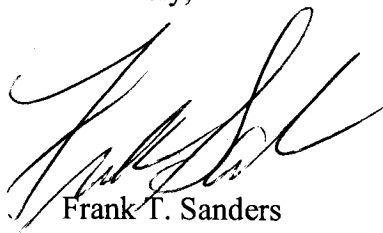
The diiodomethyl p-tolyl sulfone RED was developed through EPA's public participation process, published in the Federal Register in 2008, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the diiodomethyl p-tolyl sulfone 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, residential and ecological risks posed by exposure to diiodomethyl p-tolyl sulfone alone. This document also identifies 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 diiodomethyl p-tolyl sulfone will be eligible for reregistration provided that all the conditions identified in this document are satisfied. Sections IV and V of this RED document describe the necessary labeling amendments for end-use products and data requirements. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that will accompany this DCI.

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 Adam Heyward at (703)-308-6422.

Sincerely,

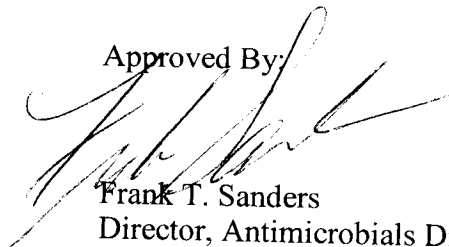
A handwritten signature in black ink, appearing to read 'Frank T. Sanders', is positioned above the printed name and title.

Frank T. Sanders
Director, Antimicrobials Division

**REREGISTRATION ELIGIBILITY
DECISION**

**for
Diodomethyl p-tolyl sulfone**
List D
CASE 4009

Approved By:

A handwritten signature in black ink, appearing to read 'Frank T. Sanders', is written over the printed name and title.

Frank T. Sanders
Director, Antimicrobials Division
March 31, 2008

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 diiodomethyl p-tolyl sulfone and is issuing its risk management decision. 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 diiodomethyl p-tolyl sulfone that pose risks of concern. As a result of this review, EPA has determined that diiodomethyl p-tolyl sulfone 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.

This document presents the Agency's revised human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for diiodomethyl p-tolyl sulfone. The diiodomethyl p-tolyl sulfone case consists of one PC Code: 101002. The first product containing diiodomethyl p-tolyl sulfone was registered in 1980. For a list of the current products, please see Appendix A.

Diiodomethyl p-tolyl sulfone is an algaecide, bactericide, and fungicide. Diiodomethyl p-tolyl sulfone is used as a materials preservative in paints, air duct coatings, fire-retardant coatings, pigment dispersions, inks, emulsions, extender slurries, adhesives, caulks, sealants, rubbers, plastic, textiles, leather, paper production to protect pulp and slurries, paper/paperboard, and wetlap. Diiodomethyl p-tolyl sulfone is also used as a wood preservative.

The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. The Agency does not anticipate dietary or drinking water exposures based on the registered use patterns and there are no tolerances or tolerance exemptions for the use of diiodomethyl p-tolyl sulfone as an active ingredient. Therefore, an FQPA hazard analysis is not necessary at this time.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of diiodomethyl p-tolyl sulfone. 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 diiodomethyl p-tolyl sulfone in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at www.regulations.gov (Docket ID EPA-HQ-OPP-2007-1151).

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 diiodomethyl p-tolyl sulfone and its regulatory history. Section III, Summary of diiodomethyl p-tolyl sulfone Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management and Reregistration, 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

Diiodomethyl p-tolyl sulfone was first registered as an active ingredient by the United States Environmental Protection Agency (EPA) on September 17, 1980. Currently, there are eight products containing diiodomethyl p-tolyl sulfone as an active ingredient. Diiodomethyl p-tolyl sulfone is an algaecide, bactericide, and fungicide. Diiodomethyl p-tolyl sulfone is used as a materials preservative in paints, air duct coatings, fire-retardant coatings, pigment dispersions, inks, emulsions, extender slurries, adhesives, caulks, sealants, rubbers, plastic, textiles, leather, paper production to protect pulp and slurries, paper/paperboard, and wetlap. Diiodomethyl p-tolyl sulfone is also used as a wood preservative.

B. Chemical Identification

Technical Diiodomethyl p-tolyl sulfone

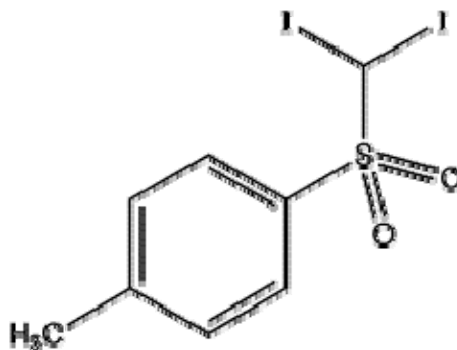


Figure #1. Molecular Structure of Diiodomethyl p-tolyl sulfone

Common name:	Diiodomethyl p-tolyl sulfone
Chemical name:	Benzene, 1-((diiodomethyl)sulfonyl)-4-methyl
Chemical family:	Sulfone, Benzene
Empirical formula:	C ₈ H ₈ I ₂ O ₂ S
CAS Registry No.:	20018-09-1
Case number:	4009
OPP Chemical Code:	101002
Molecular weight:	422.01

Other names:	Amical 48 TM ; p-Tolyl diiodomethyl sulfone; Toluene, 4-(diiodomethylsulfonyl)-; 4-Tolyl diiodomethyl sulfone; Benzene, 1-((Diiodomethyl)sulfonyl)-4-methyl; Diiodomethyl 4-tolyl sulfone; Sulfone, diiodomethyl p-tolyl; p-Methylphenyl diiodomethyl sulfone; p-Tolyl diiodomethyl sulfone
Basic manufacturer:	The Dow Chemical Company
Chemical properties:	Diiodomethyl p-tolyl sulfone is tan and is a powder at room temperature. Diiodomethyl p-tolyl sulfone has a melting point of 136° C / 149-152° C; a boiling point of 394° C; is stable at room temperature and at 54 ± 2° C for two weeks; and has a flammability of 60° C. The vapor pressure is 1.87 x 10 ⁻⁶ mm Hg/ 5.3 x 10 ⁻⁸ mm Hg at 25° C. Diiodomethyl p-tolyl sulfone has a Log Kow of 2.66, a Log Koc of 2.7838 and its solubility is 10 mg/L at 25° C in water. The Henry Law Constant is 6.03 x 10 ⁻⁷ atm-m ³ /mole. Diiodomethyl p-tolyl sulfone is persistent in air for 23.4 hours and its specific gravity is ~1 at 25° C. Diiodomethyl p-tolyl sulfone should not be used around electric equipment and has a UV-visible spectra at two absorptions peaks (200 and 233-234 nm; the spectra were run from 200-800 nm range). Diiodomethyl p-tolyl sulfone is stable for eight years at ambient temperature, stable for 36 months at 30° C and for 6 months at 40° C.

C. Use Profile

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

Type of Pesticide: Algacide, Bactericide and Fungicide

Summary of Use:

Wood Preservative:

As a wood preservative diiodomethyl p-tolyl sulfone is registered for general formulation use in wood preservative coatings and stains. Diiodomethyl p-tolyl is also registered for direct use on fresh cut wood, lumber frames, fences, decking, siding, logs, poles and wood pressure treatment.

Materials Preservative:

Diiodomethyl p-tolyl sulfone is used as a materials preservative in paints, air duct coatings, fire-retardant coatings, pigment dispersions, inks, emulsions, extender slurries, adhesives, caulks, sealants, rubbers, plastics,

textiles, leather, paper production (non-food use), paper/paperboard (non-food use) and wetlape.

Target Pests: Algae; Bacteria (causing rot or decay); Decay; Deterioration/spoilage bacteria; Fungal decay/rot; Fungal slime (of paper mills/water systems); Fungi (coatings, leather); Mildew; Mold; Sapstain; Termites; Wood rot/decay/fungi; Wood stain fungi

Formulation Types: Powder (Technical Grade Active Ingredient); Flowable dispersion, Wettable powder, and Powder (End Use Products)

Method and Rates of Application:

Equipment for Use: Diiodomethyl p-tolyl sulfone end-use products are added during the manufacturing process of treated articles and materials. Examples specific to materials preservation include: Diiodomethyl p-tolyl sulfone is added to pigment grinds and added via open pour for in-can paint and air duct coatings; Added via mixing and in-can preservation for fire-retardant coatings; Added via mixing during manufacturing for pigment dispersions, inks, emulsions and extender slurries; Added by mixing via open pour and in-can preservation for adhesives, caulks and sealants; Added during the manufacturing processes for rubbers and plastics; Added via open pour for non-clothing textiles; Added for leather tanning; Added to systems where mixing occurs for paper production; Added to whitewater or stock, the applicator rolls or showers, size press or water box for mold inhibition in paper and paperboard; Added to material to be preserved for paper plant storage. For wood preservation, diiodomethyl p-tolyl sulfone end-use products are applied via dip, dip roller, spray, pressure treatment, high pressure spray, brush, or by adding it to a water based treatment.

Application Rates: For details about specific use sites for diiodomethyl p-tolyl sulfone, refer to Appendix A.

Materials Preservatives:

- Application rates can range from
 - Paint- 0.01 lb ai/gal -0.050 lb ai/gal (flowable liquid)
 - Adhesives and Caulks- 0.01% ai per wt.- 0.29% ai per wt.
 - Leather- 0.01% ai per wt.-0.026% ai per wt. (wetable powder)

Wood Preservatives:

- Application rates can range from
 - 0.001 gal/ gal water – 0.5 gal/gal water
 - 0.05 - 2.70 lb pcf
 - 0.10% - 1% active ingredient
 - 0.30% - 2.0% active ingredient (formulate use only)

Use Classification: General use.

III. Summary of Diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2007-1151, 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 diiodomethyl p-tolyl sulfone 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 Diiodomethyl p-tolyl sulfone

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 diiodomethyl p-tolyl sulfone can be found in the "Diiodomethyl p-tolyl sulfone: Hazard Assessment," dated March 14, 2008; and the "Diiodomethyl p-tolyl sulfone. P.C. Code: 101002. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. Case 4009," dated April 29, 2008. These documents are available on the Agency's website in the EPA Docket at: <http://www.regulations.gov> (Docket ID EPA-HQ-OPP-2007-1151).

The Agency has reviewed all toxicity studies submitted for diiodomethyl p-tolyl sulfone 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 gives a summary of the acute toxicity data and the toxicological endpoints selected for the dietary exposure scenarios are summarized in Table 2.

Table #1. Summary of Acute Toxicity Data for Diiodomethyl p-tolyl sulfone

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
Acute Toxicity				
870.1100 (\$81-1)	Acute Oral	41765401 43008702 42586801	LD ₅₀ > 5000 mg/kg (for both male and female)	IV
870.1200 (\$81-2)	Acute Dermal (Rats)	00123023	LD50 (Males) > 20000 mg/kg	IV

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
870.1300 (§81-3)	Acute Inhalation	43660901 00087842	LC ₅₀ (combined)= 0.96 mg/L LC ₅₀ (male) = 1.15 mg/L LC ₅₀ (female) = 0.77 mg/L	II
870.2400 (§81-4)	Primary Eye Irritation	41765402 43008703 47354903	Severe irritant to ocular tissue of Rabbit	I
870.2500 (§81-5)	Primary Dermal Irritation	41765403 00141066	Minimum irritant to skin of Rabbit	IV
870.2600 (§81-6)	Dermal Sensitization	00054963	Not a Dermal Sensitizer	

Table #2. Dietary Toxicological Endpoints for Diiodomethyl p-tolyl sulfone

Exposure Scenario	Dose Used in Risk Assessment, UF	Target MOE, Uncertainty Factor (UF) for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all populations)	No appropriate endpoints were identified that represent a single dose effect (aRfD). Therefore, an acute dietary risk assessment is not required.		
Chronic Dietary (all populations)	Oral NOAEL= 2 mg/kg/day	UF = 1000 [10x for inter-species, 10x for intra-species, 10X for database uncertainty (missing chronic/cancer studies)]	90-day Oral (Dog) MRIDs 42054403, 43246402 NOAEL= 2 mg/kg/day, based on decreased body weight gain, decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and degeneration of the thyroid.
Carcinogenicity	There are no chronic and/or cancer studies available. Diiodomethyl p-tolyl sulfone has not been formally classified for carcinogenicity.		

Notes: UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose.

General Toxicity Observations

Acute Toxicity

Diiodomethyl p-tolyl sulfone exhibits low acute oral and acute dermal toxicity (Toxicity Category IV), and high acute inhalation toxicity (Toxicity Category II). Diiodomethyl p-tolyl sulfone is classified as an eye corrosive (Toxicity Category I). For dermal irritation, Diiodomethyl p-tolyl sulfone is a low irritant (Toxicity Category IV) and is not classified as a dermal sensitizer.

Developmental & Reproductive Toxicity

Four developmental and two reproductive studies are available for diiodomethyl p-tolyl sulfone. No clear developmental and/or reproductive toxic effects are noted in the available developmental and reproductive toxicity data. All of the effects that were noted are associated with maternal toxicity.

For the rat developmental study the following signs were noted at a dose level associated with significant maternal toxic effects: decreased mean litter size, increased number of resorptions relative to the number of implantation sites, reduced mean fetal body weight, increased incidences of umbilical hernia and incomplete ossification of the supra-occipital bones. In the rabbit developmental study there are no developmental effects at the highest dose tested of 2 mg/kg/day. In the rat reproductive studies, effects on the offspring include post-implantation loss and decreased gestation survival, decreased litter size, and decreased neonatal survival and/or pup body weight at a dose level of 10 mg/kg/day or above. However, it should be noted that offspring effects in the rat reproductive studies were noted at dosages with significant maternal effects.

The release of iodine from diiodomethyl p-tolyl sulfone is considered to result in dystocia, changes in the thyroid and pituitary in the parents, and decreased survival and pup weights in the offspring. The primary organ affected by diiodomethyl p-tolyl sulfone is the thyroid. Degeneration of the thyroid gland is noted in the 90-day dog study. Increased thyroid gland weight is noted in the rabbit and rat developmental studies. Also, histopathological changes (e.g., altered colloid staining, hypertrophy, hyperplasia and/or follicular dilatation) were noted in the rat reproductive studies.

Acute & Chronic Reference Dose (RfD)

An acute reference dose (RfD) value was not assigned for diiodomethyl p-tolyl sulfone. No appropriate endpoints were identified that represent a single dose effect for the acute dietary risk assessment. Therefore an acute dietary assessment was not conducted.

The chronic RfD value for diiodomethyl p-tolyl sulfone is 0.002 mg/kg/day for all populations. The chronic RfD was established by using an oral NOAEL of 2 mg/kg/day, which is based on a 90-day oral dog study that observed decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and thyroid degeneration. Although female dogs in the 90-day dog study had decreased mean body weight-gain from days 0 to 91 of at least 20% in comparison to the control value, the differences are within an acceptable range as is shown in historical control data.

For chronic toxicity exposure the Agency had potential concerns regarding the chronic and/or carcinogenic effects associated with diiodomethyl p-tolyl sulfone exposure. However, the Agency determined that iodine is a degradation moiety of the body once diiodomethyl p-tolyl sulfone is absorbed. Some of the effects associated with diiodomethyl p-tolyl sulfone exposure

may be associated with, but not necessarily limited to, the release of iodine in the body. For the human health risk assessment the Agency has determined that rodents are not an appropriate model for studying iodine associated effects. Therefore, the Agency believes that chronic rodent and cancer studies are not required to support the use of diiodomethyl p-tolyl sulfone at this time. To address possible chronic exposure concerns for diiodomethyl p-tolyl sulfone, an additional uncertainty factor of 10x was applied.

For diiodomethyl p-tolyl sulfone, an uncertainty factor of 1,000 was applied (10x for inter-species extrapolation; 10x for intra-species variation; and 10x for database uncertainty [missing chronic and cancer data]).

Incidental Oral Exposure

The NOAEL for the short-term incidental oral endpoint is 4 mg/kg/day. The NOAEL is based on a 30-day oral rabbit developmental toxicity study, which observed clinical signs of toxicity, reduced body weight gain, and reduced food consumption of maternal animals at a dose of 15 mg/kg/day. For the short-term incidental oral exposure, the target margin of exposure (MOE) for diiodomethyl p-tolyl sulfone is 100 (10x inter-species extrapolation; 10x intra-species variation).

For the intermediate-term incidental oral endpoint a NOAEL of 2 mg/kg/day was used. The NOAEL is based on a 90-day oral dog study, which observed decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and thyroid degeneration at a dose of 10 mg/kg/day. For intermediate-term incidental oral exposure, the target MOE for diiodomethyl p-tolyl sulfone is 100 (10x for inter-species extrapolation; 10x for intra-species variation).

Dermal Exposure

For the short-term (ST) dermal endpoint an oral NOAEL of 4 mg/kg/day was used. The NOAEL is based on an oral rabbit developmental toxicity study, which observed clinical signs of toxicity, reduced body weight-gain, and reduced food consumption at a dose of 15 mg/kg/day. The target MOE for ST dermal exposure is 100 (10x inter-species extrapolation; 10x intra-species variation).

For the intermediate-term (IT) and long-term (LT) dermal endpoints an oral NOAEL of 2 mg/kg/day was used. The oral NOAEL is based on a 90-day oral dog study, which observed decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and thyroid degeneration at a dose of 10 mg/kg/day. The target MOE for IT dermal exposure is 100 (10x for inter-species extrapolation; 10x for intra-species variation). The target MOE for LT dermal exposure is 1,000 (10x for inter-species extrapolation; 10x for intra-species variation; 10x for database uncertainty factor). However, because the technical registrant is cancelling the use of diiodomethyl p-tolyl sulfone for metalworking fluid use, there are no longer any applicable long-term dermal exposure use scenarios for diiodomethyl p-tolyl sulfone.

Because an oral dosing toxicity study was used for the dermal risk assessment, a dermal adsorption factor was calculated to be 10% based on a rat pharmacokinetic and metabolism study (MRID 47076601).

Inhalation Exposure

For the short-, intermediate-, and long-term (ST, IT, LT) inhalation exposures the endpoint was based on an oral NOAEL of 2 mg/kg/day. The NOAEL is based on a 90-day oral dog study, which observed decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and thyroid degeneration at a dose of 10 mg/kg/day. The target MOE for identifying inhalation risks of concern is 100 (10x for intra-species variation; 10x for inter-species variation) and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000 (10x for inter-species extrapolation; 10x for intra-species variation; 10x for route-to-route extrapolation). An inhalation absorption factor of 100% was used (equivalency to oral absorption was assumed) for all inhalation exposure durations since the MOE calculations are based on an oral endpoint. In cases where inhalation endpoints are set using oral toxicity data, as was done for diiodomethyl p-tolyl sulfone, the Agency will consider requiring an inhalation toxicity study to confirm that the use of route-to-route extrapolation does not underestimate risk. The Agency determines the need for confirmatory inhalation data by evaluating the inhalation MOEs. For diiodomethyl p-tolyl sulfone, if MOEs are greater than 100 but less than 1,000 confirmatory inhalation toxicity data are required to account for the use of route-to-route extrapolation. Since several inhalation MOEs are below 1,000 for diiodomethyl p-tolyl sulfone, confirmatory inhalation data are required.

Carcinogenicity

There are no chronic and/or cancer studies for diiodomethyl p-tolyl sulfone. For chronic toxicity exposure the Agency had potential concerns regarding the chronic and/or carcinogenic effects associated with diiodomethyl p-tolyl sulfone exposure. However, the Agency determined that iodine is a degradation moiety of the body once diiodomethyl p-tolyl sulfone is absorbed. Some of the effects associated with diiodomethyl p-tolyl sulfone exposure may be associated with, but not necessarily limited to, the release of iodine in the body. For the human health risk assessment the Agency has determined that rodents are not an appropriate model for studying iodine associated effects. To address possible chronic exposure concerns for diiodomethyl p-tolyl sulfone an additional uncertainty factor of 10x was applied.

Mutagenicity Potential

The mutagenicity studies for diiodomethyl p-tolyl sulfone are negative and, therefore, diiodomethyl p-tolyl sulfone is not mutagenic.

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), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency’s Endocrine Disrupting Screening Program (EDSP) have been developed, diiodomethyl p-tolyl sulfone may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. FQPA Safety Factor

The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. The Agency does not anticipate dietary or drinking water exposures based on the registered use patterns and there are no tolerances or tolerance exemptions for the use of diiodomethyl p-tolyl sulfone as an active ingredient. Therefore, an FQPA hazard analysis is not necessary at this time.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic. This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. The Agency has conducted an indirect food contact dietary exposure and risk assessment for the use of diiodomethyl p-tolyl sulfone as a materials preservative in adhesives, can-end and side-seam cements, and sealants and caulking materials for repeat use food contact surfaces.

a. Acute PAD

Acute indirect food contact dietary risk is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. An acute indirect food contact dietary assessment was not conducted for diiodomethyl p-tolyl sulfone because the use patterns are not expected to result in acute indirect food contact dietary exposure. Furthermore, no endpoints appropriate for an indirect food contact dietary risk assessment were identified in the toxicity database. Therefore, diiodomethyl p-tolyl sulfone does not pose as an indirect food contact acute dietary risk and an indirect food contact acute dietary risk assessment was not required.

b. Chronic PAD

The indirect food contact chronic dietary risk for diiodomethyl p-tolyl sulfone is assessed by comparing indirect food chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic indirect food dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose (0.002 mg/kg/day). For the adhesives preservative use, the cPAD is 14% for adults and 33% for children; for the repeat-use rubber sealants and caulking materials uses, the cPAD is 2% for adults and 5% for children; and for the can side-seam cements preservatives use, the cPAD is 6% for adults and 14% for children. The combined cPAD is 22% for adults and 52% for children. Therefore, there are no indirect food contact chronic dietary risks of concern as a result of these uses because the cPAD does not exceed the Agency's level of concern for chronic exposure durations to diiodomethyl p-tolyl sulfone.

4. Indirect Food Contact Dietary Exposure Assumptions

The Agency assessed the potential indirect food dietary and drinking water exposures and risks to diiodomethyl p-tolyl sulfone from its use as an indirect food additive. The potential indirect food dietary exposures for diiodomethyl p-tolyl sulfone are as follows: indirect food additive from paper products when used as a preservative in adhesives, can end and side-seam cements, and sealants and caulking materials for repeat use food contact surfaces.

The United States Food and Drug Administration (US FDA) has granted diiodomethyl p-tolyl sulfone indirect food clearances for the following uses:

- 175.105- Substances for use only as components of adhesives;
- 175.300- Substances for use as components of coatings- resinous and polymeric coatings (can end and side seam cements) with a limitation to not exceed 0.3% by wt in can-sealing cements;
- 176.300- Substances for use as basic components of paper and paperboard components- slimicides with a limitation to not exceed 0.2 pounds per ton of dry weight of fiber; and
- 177.2600- Substances for use as basic components of repeated use food contact surfaces- rubber articles intended for repeated use with a limitation to not exceed 0.3% by wt of sealants and caulking materials.

It should be noted that in 21CFR 176.300, US FDA has cleared the use of diiodomethyl p-tolyl sulfone as an indirect food additive for its use as a pulp and paper slimicide at a maximum level of 0.20 pound per ton of dry weight fiber. However, this use was not assessed for the reregistration eligibility decision (RED) because all of the current diiodomethyl p-tolyl sulfone labels for the pulp and paper slimicide use state for *non-food* contact paper only. Although the EPA accepts this language on the labels, examples of non-food contact paper (e.g., newsprint,

Kraft paper, brown paper mills, sheets for corrugated board, etc.) must also be listed on the appropriate labels. Most of the diiodomethyl p-tolyl sulfone labels will need to be updated to include non-food contact paper examples.

No residue data have been submitted in support of the diiodomethyl p-tolyl sulfone antimicrobial dietary uses. Therefore, a screening-level assessment has been conducted using the US FDA's Center for Food Safety & Applied Nutrition's (CFSAN) approach as presented in "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations," dated December 2007; and, memos obtained from FDA granting the diiodomethyl p-tolyl sulfone clearances. Using the maximum application rates and the US FDA's default assumptions, "worst-case" dietary concentration values were calculated by the Agency. Additional information can be found in the "Revised Dietary and Drinking Water Exposure Chapter for diiodomethyl p-tolyl sulfone for the Reregistration Eligibility Decision (RED) Document (Case 4009)," dated January 2, 2008; and the "Diiodomethyl p-tolyl sulfone. P.C. Code: 1001002. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document (Case 4009)," dated April 29, 2008.

5. Indirect Food Contact Dietary Risk Assessment

The Agency conducted an indirect food contact dietary exposure and risk assessment for the use of diiodomethyl p-tolyl sulfone as an indirect food additive in adhesives, repeat-use rubber sealants and caulking material, and can side-seam cements. Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD (aPAD or cPAD) does not exceed the Agency's risk concerns. A summary of the chronic risk estimates is shown in Table 3.

a. Dietary Risk from Indirect Food Contact

Diiodomethyl p-tolyl sulfone is used as a materials preservative, indirect food additive in adhesives, repeat-use rubber sealants and caulking material, and can side-seam cements. An acute dietary assessment was not conducted for diiodomethyl p-tolyl sulfone because the use patterns are not expected to result in acute dietary exposure and toxicity endpoints were not identified. Therefore, diiodomethyl p-tolyl sulfone does not pose as an acute dietary risk.

Utilizing the chronic PAD of 0.002 mg/kg/day, dietary risks were estimated and are summarized in Table 3 below. None of the uses exceed the Agency's level of concern for the chronic exposure durations. Therefore, there are no chronic dietary risks of concern for treated adhesives, repeat-use rubber sealants and caulking material, and can side-seam cements.

Table #3. Dietary Risks of Diiodomethyl p-tolyl sulfone Indirect Food Uses

FDA Clearance (21 CFR §)	Use	Dose (mg/kg/day)		% cPAD	
		Adult	Child	Adult	Child
175.105	Preservative in Adhesives	0.00029	0.00067	14%	33%
177.2600	Preservative in Repeat-use Rubber Sealants and Caulking Materials	0.000043	0.00010	2%	5%
175.300	Preservative in Can Side-Seam Cements	0.00012	0.00027	6%	14%
	Combined	0.0004	0.0010	22%	52%

% cPAD = exposure/ cPAD x 100

b. Dietary Risk from Drinking Water

Diiodomethyl p-tolyl sulfone is not used for water treatment and the active ingredient is not expected to contact fresh water environments. Also, the wood preservation use of diiodomethyl p-tolyl is for terrestrial use only, and is not expected to contact aquatic environments provided that the appropriate label language and mitigation measures outlined in chapters IV and V of this document are implemented. Based on the use patterns, the potential for diiodomethyl p-tolyl sulfone to impact drinking water sources is negligible. Therefore, a drinking water assessment was not conducted.

6. Residential Risk Assessment

Based on registered use patterns from product labels, it has been determined that exposure to residential handlers or applicators can occur in a variety of residential environments. Additionally, post-application exposures are likely to occur in these settings. The representative scenarios selected by the Agency for assessment were evaluated using maximum application rates as stated on the product labels. The residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food and drinking water. Exposure may occur during application for several use patterns including painting/applying wood preservative via brush/roller and airless sprayer. In addition, toddlers may be exposed to diiodomethyl p-tolyl sulfone when using finger paints preserved with this active ingredient. Post-application exposure may occur from dermal and incidental oral contact with treated lumber (playground equipment or decking) or through incidental oral contact with finger-paint. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose. Additional information can be found in the

“Occupational and Residential Exposure Chapter for Diiodomethyl p-tolyl sulfone,” dated March 27, 2008; and the “Diiodomethyl p-tolyl sulfone. PC Code: 101002. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. Case 4009,” dated April 29, 2008.

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary, residential and occupational risks for diiodomethyl p-tolyl sulfone are listed in Table 4.

For the residential handler assessment, a Margin of Exposure (MOE) greater than or equal to 100 is considered adequately protective for short-term (ST) and intermediate-term (IT) dermal exposures. The MOE of 100 includes an uncertainty factor (UF) of 10x for inter-species extrapolation and 10x for intra-species variation.

For inhalation exposure the target MOE for identifying inhalation risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000. An UF of 10x for inter-species extrapolation, 10x for intra-species variation and 10x for route-to-route extrapolation was applied. However, if an inhalation MOE of 1,000 is not achieved a route-specific inhalation toxicity study is needed to confirm that the use of route-to-route extrapolation does not underestimate risk.

For the ST and IT incidental oral exposure an MOE greater then or equal to 100 is considered adequately protective. An UF of 10x for inter-species extrapolation and 10x for intra-species variation was applied.

Table #4. Residential and Occupational Toxicological Doses and Endpoints for Diiodomethyl p-tolyl sulfone

Exposure Scenario	Dose Used in Risk Assessment	Target MOE/ UF, for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short-Term (1-30 days)	Oral Maternal NOAEL =4 mg/kg/day	UF = 100 (10x for inter-species, 10x for intra-species)	Rabbit Developmental Toxicity (MRID 42243801 and 43246404) Based on clinical signs, reduced body weight gain and food consumption.
Incidental Oral Intermediate-Term (1- 6 months)	Oral NOAEL =2 mg/kg/day	MOE = 100 (10x for inter-species, 10x for intra-species)	90-day Oral (Dog) MRID 42054403 and 43246402 Based on decreased body weight gain, decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and degeneration of the thyroid.
Dermal Absorption Factor	10% Based on the Rat Pharmacokinetics and Metabolism data (MRID 47076641).		

Exposure Scenario	Dose Used in Risk Assessment	Target MOE/ UF, for Risk Assessment	Study and Toxicological Effects
Dermal System, Short-Term (1-30 days)	Oral Maternal NOAEL =4 mg/kg/day	MOE = 100 (10x for inter-species, 10x for intra-species)	Rabbit Developmental Toxicity (MRID 42243801 and 43246404) Based on clinical signs, reduced body weight gain and food consumption.
Dermal Intermediate-Term (1- 6 months)	Oral NOAEL = 2 mg/kg/day	MOE = 100 (10x for inter-species, 10x for intra-species)	90-day Oral (Dog) MRIDs 42054403 and 43246402 Based on decreased body weight gain, decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and degeneration of the thyroid.
Dermal¹ Long-Term (>6 months)	Oral NOAEL =2 mg/kg/day	MOE = 1,000 (10x for inter-species, 10x for intra-species, 10x for database uncertainty [missing chronic/cancer and reproductive studies])	90-day Oral (Dog) MRID 42054403 and 43246402 Based on decreased body weight gain, decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and degeneration of the thyroid. Based on lymphocytic infiltration in females and erosion of gastric mucosa and prominence of limiting ridge of the stomach in males.
Inhalation² All Exposure Terms	Oral NOAEL =2 mg/kg/day	MOE = 1,000 (10x for inter-species, 10x for intra-species, 10x for route-to-route extrapolation)	90-day Oral (Dog) MRID 42054403 and 43246402 Based on decreased body weight gain, decreased activity, dehydration, mucoid ocular discharge, weakened appearance, abnormal feces, and degeneration of the thyroid. Lymphocytic infiltration in females and erosion of gastric mucosa and prominence of limiting ridge of the stomach in males.
Cancer (oral, dermal, inhalation)	No cancer data are available		

¹ The registrant has requested voluntary cancellation of the metalworking fluid uses. There are no long-term dermal exposure scenarios as a result of this use cancellation.

² The inhalation absorption factor of 100% (default value, assuming oral and inhalation absorption are equivalent) should be used since an oral endpoint was selected for the inhalation exposure scenarios. If results are below an MOE of 1,000, confirmatory inhalation toxicity data are warranted.

UF = Uncertainty Factor, NOAEL = No Observed Adverse Effect Level, LOAEL = Lowest Observed Adverse Effect Level, PAD = Population Adjusted Dose (a = acute, c = chronic) RfD = Reference Dose, MOE = Margin Of Exposure, LOC = Level Of Concern, NA = Not Applicable

b. Residential Handlers

i. Exposure Assessment

Residential handler exposure to diiodomethyl p-tolyl sulfone can occur through the application of treated paints via brush, roller, and airless sprayer; and the application of wood preservatives to treat wood surfaces via brush, roller and airless sprayer. In addition, toddlers may be exposed to diiodomethyl p-tolyl sulfone when using finger paints preserved with this active ingredient. The residential exposure scenarios assessed for diiodomethyl p-tolyl sulfone represent worst case exposure scenarios. The EPA selected high-end representative use scenarios based on maximum application rates as stated on the product labels. The residential handler exposure use scenarios assessed are shown in Table 5. This table also shows the maximum application rates associated with the representative uses and the EPA Registration numbers for the corresponding product labels.

Table #5. Representative Uses Associated with Residential Handler Exposure

Representative Use	Exposure Scenario	Application Method	EPA Reg. No.	Maximum Application Rate
Applying Wood Preservatives on Decks	<u>ST Handler</u> : Adult Dermal and Inhalation	Paint brush, Roller, Airless-sprayer	60061-9	0.00021 lb ai/sq ft (8.34 lb/gal x 0.38% ai x 1 gal /150 sq. ft)
Applying Treated Paints (in-can preservative)	<u>ST Handler</u> : Adult Dermal and Inhalation	Paint brush, Roller, Airless-sprayer	464-672	0.050 lb ai/gal (10.2 lb/100 gal x 48.45%)
Two Hand Immersion (Toddler Finger-Painting)	<u>ST Handler</u> : Child Dermal	Finger-Painting	NA	NA

Note: Only EPA registered products with specified use directions/use applications are included in this table.

Products listed were selected based on maximum use rates by application method.

ST = Short-term exposure

*Handler dermal and inhalation exposure were assessed using PHED unit exposures.

Dermal and inhalation exposures were assessed for these scenarios using the Pesticide Handler Exposure Database (PHED, Version 1.1) and values were found in the EPA's *Standard Operating Procedures (SOP) for Residential Exposure Assessments* (U.S. EPA, 1997a, 2001). The dermal and inhalation exposures from these techniques have been normalized by the amount of active ingredient handled and are reported as unit exposures (UE), which are expressed as mg/lb of active ingredient handled.

Surrogate unit exposure data, maximum application rates from labels, and EPA estimates

of daily amounts handled were used to assess residential handler exposures and risks. The residential handler scenarios were assumed to be of short-term duration (1-30 days).

ii. Risk Assessment

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation risk assessments for residential handler exposure. An MOE greater than or equal to 100 is considered adequately protective for the dermal route of exposure.

For inhalation exposure the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However, if the inhalation MOE is greater than 100 but less than 1,000, inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation does not underestimate inhalation exposure risk. For diiodomethyl p-tolyl sulfone the inhalation endpoint was set using oral toxicity data. When oral toxicity data are used to select an inhalation endpoint, as was done for diiodomethyl p-tolyl sulfone, the Agency considers requiring inhalation toxicity data to confirm that the use of route-to-route extrapolation does not underestimate potential risk.

For the residential handler risk assessment the calculated dermal and inhalation MOEs are all above their respective target MOEs of 100, except for the following use scenario. The following residential exposure scenario indicates risks of concern:

- Painting: Airless Sprayer
(ST Dermal MOE = 48)

An inhalation toxicity study is needed to confirm that there are no inhalation risks of concern because the inhalation MOE for painting via airless sprayer (MOE = 230) is below the high-end target of 1,000. A summary of the residential handler exposures and risks are presented in Table 6.

Table #6. Short-Term Residential Handler Exposures and MOEs

	Method of Application	Unit Exposure (mg/lb ai)		Application Rate	Quantity Handled/ Treated per day	Absorbed Daily Dose (mg/kg/day)		MOE	
		Dermal ^a	Inhalation			Dermal ^b	Inhalation ^c	Dermal	Inhalation
								ST (Target=100) ^d	(Target = 100) ^e
Wood Preservative	Brush/roller	230	0.284	0.00021 lb ai/sq ft	300 sq ft	2.52E-2	2.6E-4	192	7800
	Airless sprayer	79	0.83	0.00021 lb ai/sq ft	300 sq ft	8.6E-3	7.5E-4	559	2700
Painting	Brush/roller	230	0.284	0.05 lb ai/gal	2 gal	3.9E-2	4.0E-4	123	5000

	Airless sprayer	79	0.83	0.05 lb ai/gal	15 gal	1.0E-1	8.8E-3	48	230
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- a All dermal unit exposures represent ungloved replicates. The brush/roller, and airless sprayer unit exposures represent short sleeve and short pant replicates.
- b Dermal Daily Dose (mg/kg/day) = [dermal unit exposure (mg/lb ai) * application rate * quantity handled * ABS (0.12) / body weight (70 kg).
- c Inhalation Daily Dose (mg/kg/day) = [inhalation unit exposure (mg/lb ai) * application rate * quantity handled / body weight (70 kg).
- d Dermal MOE = NOAEL (mg/kg/day) / Daily Dose. Target dermal MOE is 100 for ST and 300 for IT (ST NOAEL 4 mg/kg/day and IT LOAEL 2 mg/kg/day).
- e Inhalation MOE = LOAEL (2 mg/kg/day) / Daily Dose. Target inhalation MOE is 300.

In addition to painting activities, children may have dermal exposure as a result of handling treated finger-paint. Therefore, a short-term dermal exposure assessment was conducted to assess potential dermal risks to children from finger-painting. For this exposure scenario, it was assumed that the amount of treated paint present on the painter's skin could be represented by an estimate of the paint remaining on hands (i.e., wet film thickness) following complete immersion into the paint with some wiping since the toxicological endpoint is a systemic effect. For short-term durations, the film thickness of the paint on the hands was based on a study in which both hands were dipped in mineral oil and then partially cleaned with a rag (US EPA 1992). The film thickness value of 1.75 mg/cm² (partial wipe) was chosen because the dermal endpoint for short-term durations is based on systemic effects and represents an estimate in the absence of more specific data. However, the density of the finger-paint was assumed to be somewhat higher than oil/water. Therefore, to bracket the risk, a worst-case estimate for film thickness residue data (10.3 mg/cm²) for the amount remaining after immersion of hands in mineral oil was assumed. The calculated short-term dermal MOEs are above the target MOE of 100 and, therefore, are not of concern. A summary of the short-term dermal exposures and MOEs for toddlers' finger painting can be found in table 7.

Table #7. Short-term Dermal Exposures and MOEs for Toddlers Finger-Painting

Exposure Scenario	% ai	Film thickness (mg/cm ²)	Frequency (events/day)	Hand Surface Area (cm ²)	PDR ^a (mg/mg/kg/day)	ST MOE ^b (Target MOE=100)
Painter - two hand immersion	0.06	10.3	1	350	0.0034	118
		1.75	1	350	0.0057	695

a PDR= (% ai x FT x FQx SA x ABS)/BW. Dermal absorption or ABS is 12%.

b MOE = NOAEL (mg/kg/day) / Potential dose rate (mg/kg/day) [Where: ST NOAEL = 4 mg/kg/day, Table 3.2].

c. Residential Post-application

i. Exposure Assessment

Residential post-application exposures result when adults and children come in contact with diiodomethyl p-tolyl sulfone in areas where pesticide end-use products have recently been applied (e.g., treated wood), or when children incidentally ingest the pesticide residues through mouthing the treated end-products/treated articles (i.e., hand-to-mouth or object-to-mouth contact).

Post-application scenarios have been developed to encompass potential high-end exposures from various wood and materials preservative products. Representative post-application scenarios assessed include children contacting treated wood (dermal and incidental oral exposure). Post-application residential inhalation exposure risks of concern were not assessed because diiodomethyl p-tolyl sulfone has a relatively low vapor pressure (less than 1E-6 mm Hg) and, therefore, post-application inhalation exposure is expected to be negligible.

It should be noted that the registrant has indicated that they do not intend to support the use of treated polymers/plastics for the use as toy products. The Agency requires the following label language for treated polymer/plastics labels to ensure that these products are not used to manufacture toys, "Treated plastics can not be used to manufacture children's toys." If labels are not amended to include this language, a risk assessment will be required for the use of diiodomethyl p-tolyl sulfone in plastic/polymer toys.

At this time, the Agency does not have residue dissipation data or reliable use pattern data, including the frequency and duration of use of antimicrobial products in the residential setting. Therefore, to assess residential handler and post-application risks, the Agency used surrogate unit exposure data from the following proprietary resources: Chemical Manufacturers Association (CMA) antimicrobial exposure study; the Pesticide Handlers Exposure Database (PHED); Stochastic Human Exposure and Dose Simulation (SHEDS) model (USEPA 2005a); and the proprietary sapstain study (task force # 73154), *Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)* (Bestari et al., 1999, MRID 455243-04). Additionally, the EPA's Health Effects Division's (HED) *Standard Operating Procedures (SOPs) for Residential Exposure Assessments*, was used when estimating post-application/ bystander exposures.

Treated Carpet

The technical registrant for diiodomethyl p-tolyl sulfone has indicated that diiodomethyl p-tolyl sulfone is intended to treat carpet-backing only, not carpet fiber. The use of diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone in carpets, to carpet-backing only, by adding limitation language to the labels. As a result of the cancellation of the use of diiodomethyl p-tolyl sulfone to treat carpet fibers, and label language limiting the use of diiodomethyl p-tolyl sulfone to treat carpet-backing only, the Agency has determined that

a post-application residential risk assessment is not needed to assess risks from treated carpet-backing. The rationale 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 diiodomethyl p-tolyl sulfone 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. However, if the carpet fiber use is not cancelled and labels are not amended to restrict the use of diiodomethyl p-tolyl sulfone to carpet-backing only, the Agency will have to assess possible exposure resulting from the use of diiodomethyl p-tolyl sulfone in carpet fiber.

Treated Lumber

A number of diiodomethyl p-tolyl sulfone end-use products are registered for wood preservative uses in pressure and non-pressure treatments of wood products intended for residential applications. As a result of these uses, there is potential for post-application exposure to individuals exposed to diiodomethyl p-tolyl sulfone treated wood in residential settings.

Typical uses for diiodomethyl p-tolyl sulfone end-use wood preservative products include building lumber, furniture, frames, fences, decking, shingles, siding, logs and poles. Incidental ingestion exposure for adults is expected to be negligible and dermal contact for adults is expected to be lower than exposure for children crawling on wood decks. Because children are more likely than adults to contact wood surfaces using playground equipment (play-sets) and because children have a higher surface area to body weight ratio, they have been used to represent the maximum exposed individual.

There are no available data to assess the levels of diiodomethyl p-tolyl sulfone residues in soil contaminated from treated wood (above ground fabricated components of decks or play-sets). Because of this data gap, the Agency was not able to estimate dermal and incidental ingestion residential post-application exposures to soil contaminated with diiodomethyl p-tolyl sulfone treated wood. There are also no data that can be used to estimate either exposure to adults from inhalation of wood dust during construction of wood decks or to children exposure to treated wood.

As previously mentioned, there are no chemical-specific surface wipe residue data available to assess the dermal and incidental exposure for children playing on treated structures. As a result of this lack of data, the Agency conducted a screening-level assessment of incidental ingestion and dermal exposures to children from contact with treated wood using surrogate data. For the reregistration decision, a conservative surface residue value of $1 \mu\text{g}/\text{cm}^2$ was used. The $1 \mu\text{g}/\text{cm}^2$ value accounts for the skin reduction factor, or “transfer efficiency” from a cloth wipe (e.g., cloth wipe surface residues are higher than that available to the skin). This high-end residue value is higher than the maximum residue seen for chromium and non chromium-based wood preservatives. The deterministic screening-level assessment was developed by the EPA to assess children’s exposure using the $1 \mu\text{g}/\text{cm}^2$ wood residue value along with exposure algorithms and parameters from the probabilistic Stochastic Human Exposure and Dose Simulation (SHEDS) model (USEPA 2005a). SHEDS was developed by the EPA to assess

exposure to children contacting CCA-treated structures (i.e., decks and play sets). The SHEDS report along with the EPA's response to the Science Advisory Panel's (SAP) review comments is located at http://www.epa.gov/heads/sheds/cca_treated.htm.

Based on the results of the CCA assessment and preliminary calculations for diiodomethyl p-tolyl sulfone, direct contact with treated wood exhibits the highest potential for exposure. The leaching of wood preservative into the soil and subsequent exposure is less than that attributed to direct contact with the treated wood itself. Therefore, for screening-level assessment purposes, only contact with treated wood is quantified. If the risks are not of concern for contacting the treated wood directly, then the soil exposure and aggregate of the soil exposure with the direct wood exposure is expected to be of minimal additional contribution.

Diiodomethyl p-tolyl sulfone is used to treat dimensional lumber, and potential dermal exposure to children can result from playing on diiodomethyl p-tolyl sulfone treated structures such as decks and/or play sets. The dermal and incidental oral toxicological endpoints of concern for Diiodomethyl-p-tolyl sulfone are non-cancerous. Therefore, the amortization of exposure over time that is provided in the SHEDS model for CCA is not appropriate for diiodomethyl p-tolyl sulfone. The frequency of exposure is believed to be best represented by the short-term (ST) duration (e.g., 1 to 30 days of continuous exposure). However, intermediate-term (IT) durations were also calculated to provide risk estimates for that portion of the population that plays continuously on treated structures up to 6 months at a time. A surface residue wipe study is required to confirm the findings of the screening level assessment conducted by the Agency.

Treated HVACs

Post-application/ bystander inhalation exposure was not assessed for the use of diiodomethyl p-tolyl sulfone to treat HVAC systems because bystander exposure is expected to be negligible. Additional HVAC use information was obtained by the registrant during the Phase III public comment period (MRID 473073-12). According to the technical registrant, the product is robotically sprayed inside HVAC air ducts and there is no airflow in the ducts during spraying. The product is allowed to dry for 2 hours. When HVAC systems turn on, any diiodomethyl p-tolyl sulfone vapor in the ducts is vented into buildings and mixed with room air. The vapor pressure is $6.9\text{E-}6$ Pa at 25C ($5.2\text{E-}8$ mm Hg at 25C) (MRID 472340-04). Therefore, based on the refined use pattern presented by the registrant, post-application inhalation exposures are expected to be negligible and therefore, an assessment for this use is not needed nor included in this document.

Hand-to-Mouth from Finger Painting

During finger painting activities, children may have incidental oral exposure via hand-to-mouth activity. The Agency did not have estimates of exactly how much finger paint a child would ingest per day. At the time of this assessment, the Agency did not have the exact density of finger paint solution since it was not initially specified on any of the labels. It should be noted

that the registrants did provide information to verify the concentration of active ingredient in finger paint. Therefore, in order to see if this route of exposure could pose as a risk of concern, the Agency back-calculated the acceptable short-term ingestion dose to estimate the amounts of finger painting that would be acceptable given the NOAEL of 4 mg/kg/day and the target MOE of 100. The Agency back-calculated that 960 mg (or 0.96 grams) of finger paint ingested could trigger a potential concern for Diiodomethyl-p-tolyl sulfone. The Agency commonly assumes for example that 1 to 1.5 grams of toothpaste gel is applied to a toothbrush. Given, that finger paint is a gel similar to toothpaste; the Agency believes that it is reasonable to assume that a child could potentially ingest 1 to 1.5 grams of finger paint.

Table 8 presents the residential post-application scenarios evaluated by the Agency. These scenarios are considered to be representative of all possible post-application residential exposure scenarios.

Table #8. Representative Uses Associated with Residential Post-Application Exposure

Representative Use	Exposure Scenario	Application Method	EPA. Reg. No.	Maximum Application Rate
HVAC Air Duct Coatings ³	<u>ST Bystander:</u> Child Inhalation	Sprayer	464-672	0.05 lb ai/gal (10.2 lb ai/100 gal x 48.45%)
Wood Preservatives on Decks	<u>ST/IT Post-app:</u> Child dermal, incidental ingestion	NA	60061-9	0.00021 lb ai/sq ft (8.34 lb/gal x 0.38% ai x 1 gal /150 sq. ft)
Textiles (i.e. carpets)	<u>ST/IT Post-app:</u> Child dermal, incidental ingestion	NA	464-670	0.00475 lb ai/lb dry fabric (5 lb per 1000 lb dry fabric x 95%)
Finger-Painting	<u>ST Handler:</u> Child Oral	Finger-Painting	NA	NA

ii. Risk Assessment

Based on toxicological criteria and potential for exposure, the Agency has conducted a residential post-application assessment for dermal and incidental oral exposure scenarios. An MOE greater than or equal to 100 is considered adequately protective for short-term (ST) and intermediate-term (IT) dermal and incidental oral exposures.

³ Post-application residential inhalation exposure risks of concern were not assessed because diiodomethyl p-tolyl sulfone has a relatively low vapor pressure (less than 1E-6 mm Hg) and, therefore, post-application inhalation exposure is expected to be negligible. Post-application inhalation exposures are expected to be negligible for the use of diiodomethyl p-tolyl sulfone to treat HVAC systems. Therefore, an assessment for this use is not included in this document.

For the residential post-application risk assessment, MOEs are above their respective target MOEs of 100 for all but one of the exposure scenarios. Incidental oral risks of concern were identified for post-application exposure of children to finger-paint. Using 1.5 grams of finger paint and a NOAEL of 4 mg/kg/day, the resulting incidental oral MOE ranges from 65-100. Therefore, there are incidental oral risks of concern for the finger-painting use scenario.

For further information regarding the post-application exposures and risk estimates for children exposed to treated lumber and finger-paint please refer to Table 9.

Table #9. Residential Post-application Risks for Children

	Dermal MOE (Target 100 ST/ IT)	Incidental Oral MOE (Target 100 ST/ IT)
Child Contacting Treated Wood	ST MOE = 237 @ 1 ug/cm ² IT MOE = 119 @ 1 ug/cm ²	ST MOE = 710 @ 1 ug/cm ² IT MOE = 355 @ 1 ug/cm ²
Child Hand-to-Mouth Exposure from Finger-Painting	NA	ST MOE = 65-100

7. 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.

Dietary and non-dietary aggregate assessments were conducted for diiodomethyl p-tolyl sulfone. When selecting the exposure scenarios for the aggregate assessment, the use patterns of diiodomethyl p-tolyl sulfone and the probability of co-occurrence were considered. The following use scenarios were selected for the dietary and non-dietary aggregate exposure assessment:

Aggregate Exposure Assessment- Dietary Scenarios for Children

- Chronic dietary exposure from combined indirect food uses
- Post-application incidental oral exposure to wood preservatives in residential settings

Aggregate Exposure Assessment- Non-Dietary Scenarios for Children

- Dermal exposure to finger-paint treated with diiodomethyl p-tolyl sulfone
- Post-application dermal exposure to wood preservatives in residential settings
- Incidental oral exposure to finger-paint treated with diiodomethyl p-tolyl sulfone
- Post-application incidental oral exposure to wood preservatives in residential settings

Table 10 summarizes the short- and intermediate-term aggregate exposure scenarios that were assessed.

Table #10. Short-term and Intermediate-term Aggregate Exposure Use Scenarios

	Short-term Aggregate	Intermediate-Term Aggregate
Children	Dermal: <ul style="list-style-type: none"> • Handler exposure to diiodomethyl-p-tolylsulfone for finger painting activities • Post-application exposure to diiodomethyl-p-tolylsulfone from wood preservatives used in decks 	Dermal: <ul style="list-style-type: none"> • Post-application exposure to diiodomethyl-p-tolylsulfone from wood preservatives used in decks
	Incidental Oral: <ul style="list-style-type: none"> • Post-application hand-to-mouth exposure to wood preservatives on decks • Post-application hand-to-mouth exposure from finger-painting 	Incidental Oral: <ul style="list-style-type: none"> • Post-application hand-to-mouth exposure to wood preservatives on decks • Chronic dietary exposure from indirect food use

Intermediate Dietary Aggregate Risk

An aggregate assessment for children was conducted for chronic dietary exposure from the indirect dietary food uses of diiodomethyl p-tolyl sulfone and from intermediate-term post-application incidental oral exposure to treated wood in residential settings. In order to accommodate the dissimilar uncertainty factors between intermediate-term residential exposure and long-term dietary exposure an aggregate risk index (ARI) approach was utilized. An ARI less than 1 indicates risks of concern. For diiodomethyl p-tolyl sulfone, the ARI is 1.6 and, therefore, there are no aggregate risks of concern for incidental oral exposure to treated wood and chronic dietary exposure from indirect food use. Please refer to Table 11 for further information regarding the aggregate risk assessment for incidental oral and indirect dietary exposure of children to diiodomethyl p-tolyl sulfone.

Table #11. Aggregate Risk Assessment for Incidental Oral and Indirect Dietary Exposure to Children

Exposure Routes	Exposure (mg/kg/day)	Margin of Exposure	Uncertainty Factor (UF)	Risk Index (RI)	ARI ^a
Incidental oral aggregate					
- dietary	0.00067	2990	1000	3.0	1.6
-hand-to-mouth wood	0.0056	355	100	3.6	

a: Aggregate MOE = $1 / ((1/RI \text{ incidental oral}) + (1/RI \text{ products}))$ where MOE = NOAEL (mg/kg/day) / absorbed daily dose (mg/kg/day) [Oral NOAEL (systemic): 2 mg/kg/day].

Short- and Intermediate-term Non-Dietary Aggregate Risk

A short-term (ST) aggregate assessment for adults was not performed for diiodomethyl p-tolyl sulfone because of a low-probability for exposure and co-occurrence. When selecting the exposure scenarios for the aggregate assessment, the use patterns of diiodomethyl p-tolyl sulfone and the probability of co-occurrence were considered. Residential painting and wood preserving activities are expected to occur only once or twice a year. The probability of co-occurrence and the potential for exposure to residues from these uses with other diiodomethyl p-tolyl sulfone products on the same day is highly unlikely. Therefore, ST adult exposure scenarios were not aggregated for diiodomethyl p-tolyl sulfone. An IT aggregate exposure assessment was not conducted for adults because there are no IT use scenarios for diiodomethyl p-tolyl sulfone.

An aggregate assessment was not conducted for inhalation exposure because diiodomethyl p-tolyl sulfone has a relatively low vapor pressure and, therefore, post-application inhalation exposure is expected to be negligible.

For toddlers, aggregation 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, it was possible to aggregate route specific exposures (e.g., incidental oral aggregate assessment and dermal aggregate assessment). An aggregate assessment was conducted for ST dermal exposures of children to treated finger-paint and treated wood decks. The total MOE for the ST dermal aggregate exposure assessment (MOE = 237) is above the target of 100 and therefore, not of concern. An aggregate assessment was not conducted for intermediate-term (IT) dermal exposure of children because the finger-painting use pattern is not expected to occur on an IT basis. Results of the short-term dermal aggregate assessment for toddlers/children are presented in Table 12.

Table #12. Short-term Dermal Aggregate Assessment for Children

Exposure Route	MOEs			
	Wood	Finger painting	Aggregate	Target MOE
Dermal (Child)	237	695	237	100

a: Aggregate MOE = $1/((1/\text{MOE}_{\text{wood}}) + (1/\text{MOE}_{\text{fingerpainting}}))$

An aggregate assessment was not conducted for short- and intermediate-term incidental oral exposure of children because there are individual risks of concern for hand-to-mouth exposure from treated finger-painting (MOE = 65-100). An incidental oral aggregate assessment would only reflect the previously identified risks of concern and incorporation of this scenario into an aggregate assessment would result in risks of concern. Therefore, an incidental oral exposure assessment was not conducted.

8. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, applying a pesticide, or re-entering treated sites. Diiodomethyl p-tolyl sulfone is used as a materials and wood preservative. Potential occupational handler exposure can occur in various use sites during the

preservation of materials that are used for household, institutional, and industrial uses; and the preservation of wood.

The “preservation of materials” refers to the scenario of a worker adding the preservative to the material being treated (paint, textiles, etc.) through either liquid pour or liquid pump methods. For the preservation of wood at treatment plants and lumber mills, the methods for treatment can vary (pressure/non-pressure), such that multiple worker functions were analyzed.

The representative uses assessed include the following materials preservative and wood preservative incorporation and application methods: mixing and loading of product concentrates for materials preservative incorporation into paint, paper (production), adhesives/caulks, emulsion, leather, plastics/rubber, slurries, textiles, and air duct coatings (liquid pour, liquid pump, open pour wettable powder, sprayer); application of treated paint (paint brush, roller, and airless sprayer); and application of protective wood coatings (pressure treatment, brush, airless sprayer, dip-non-pressure treatment).

a. Occupational Toxicity

The toxicological endpoints used in the occupational handler assessment of diiodomethyl p-tolyl sulfone can be found in Table 4, “Residential and Occupational Toxicological Doses and Endpoints for Diiodomethyl p-tolyl sulfone,” 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.

The Agency evaluated representative scenarios using maximum application rates as recommended on diiodomethyl p-tolyl sulfone product labels. It should be noted that for the calculation of application rates in which 8.34 lb active ingredient/gal is noted, the product is assumed to have the density of water because no product-specific density is available. To assess handler risk, the Agency used surrogate unit exposure data primarily from 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.

In lieu of chemical-specific data available regarding typical exposures to diiodomethyl p-tolyl sulfone as a wood preservative, surrogate data were used to estimate exposure and risks. The blender/spray operator position was assessed using CMA unit exposure data and the

remaining handler and post-application positions were assessed using data from the proprietary study, *“Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)”* (Bestari et al., 1999, MRID 455243-04). It is assumed that the workers at facilities using diiodomethyl p-tolyl sulfone wood preservatives and handling the treated wood are performing similar tasks as those monitored in the DDAC study. Dermal and inhalation exposures for treated wood pressure treatment uses were derived from information in the exposure study sponsored by the American Chemistry Council (2002) entitled, *“Assessment of Potential Inhalation and Dermal Exposure Associated with Pressure Treatment of Wood with Arsenical Wood Products”* (ACC, 2002).

The durations and routes of exposure evaluated for occupational exposure of diiodomethyl p-tolyl sulfone include: short-term (ST) (1 to 30 days) and intermediate-term (IT-30 days to 6 months) dermal and inhalation routes of exposure for the occupational scenarios.

For more information on the assumptions and calculations of the potential risks of diiodomethyl p-tolyl sulfone to workers, refer to the “Diiodomethyl p-tolyl sulfone. P.C. Code: 101002. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. Case 4009,” dated April 29, 2008 and the “Occupational and Residential Exposure Chapter for Diiodomethyl p-tolyl sulfone,” dated March 27, 2008. Based on the representative use patterns of diiodomethyl p-tolyl sulfone, the exposure scenarios in Table 13 were assessed:

Table #13. Representative Exposure Scenarios Associated with Occupational Exposures to Diiodomethyl p-tolyl sulfone

Representative Use	Method of Application	Exposure Scenario	EPA Reg. No.	Maximum Application Rate
Materials Preservatives				
Paint	<u>Preservation of paint</u> Liquid pour Liquid pump <u>Professional painter</u> Brush/Roller Airless sprayer	<u>IT and ST Handler:</u> dermal and inhalation <u>ST Prof Painter:</u> dermal and inhalation (aerosol and vapor)	464-672 464-673	0.049 lb ai/gal wettable powder (WP) 0.049 lb ai/gal flowable liquid (F)
Air Duct Coatings	Sprayer	<u>IT and ST Handler:</u> inhalation Bystander inhalation	464-672	0.049 lb ai/gal
Paper production	Liquid pump	<u>IT and ST Handler:</u> dermal and inhalation	464-672 464-673	0.775 lb ai/ton WP 0.768 lb ai/ton F

Representative Use	Method of Application	Exposure Scenario	EPA Reg. No.	Maximum Application Rate
Adhesives and Caulks	Liquid pour Liquid pump	<u>IT and ST Handler:</u> dermal and inhalation	464-672 464-673	0.29% ai per wt. F 0.30% ai per wt. WP
Emulsions	Liquid pour Liquid pump	<u>IT and ST Handler:</u> dermal and inhalation	464-672 464-673	0.14 % ai per wt. F 0.15% ai per wt. WP
Leather	Liquid pour Liquid pump	<u>IT and ST Handler:</u> dermal and inhalation	464-672 464-673	0.26% ai per wt. F 0.296% ai per wt. WP
Plastics Rubbers	Liquid pour Liquid pump	<u>IT and ST Handler:</u> dermal and inhalation	464-672 464-673	0.026% ai per wt. F 0.278% ai per wt. WP
Slurries	Liquid pour Liquid pump	<u>IT and ST Handler:</u> dermal and inhalation	464-672 464-673	0.15% ai per wt. F and WP
Textiles	Liquid pour Liquid pump	<u>IT and ST Handler:</u> dermal and inhalation	464-672 464-673	0.0048 lb ai/lb dry wt. F 0.005 lb ai/lb dry wt. WP
Wood Preservatives				
Wood Preservative (pressure and non-pressure treated)	Pressure Treatment Brush Airless Sprayer Dip (Non-Pressure Treatment)	<u>IT and ST Handler & Post-application:</u> dermal and inhalation	464-673 (pressure treatment) 60061-009 (brush/airless sprayer)	0.4 lb ai/cubic ft (pressure treatment) 0.00021 lb ai/sq ft (brush/airless sprayer)

Note: Only EPA registered products with specified use directions/use applications are included in this table. Products listed were selected based on maximum use rates by application method.
ST = Short-term exposure, IT = Intermediate-term exposure, LT= Long-term exposure.

c. Occupational Handler Risk Summary

The occupational handler risk assessment for diiodomethyl p-tolyl sulfone includes both inhalation and dermal exposure scenarios. The target MOE for short- and intermediate- term (ST/ IT) dermal exposure is 100. For inhalation exposure the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However, if the inhalation MOE is greater than 100 but less than 1,000, inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation does not underestimate inhalation exposure risk.

Materials Preservation & Application- Occupational Handler Risk Summary

For occupational handlers the use of PPE is required on all product labels. Without the use of PPE several dermal and inhalation risks of concern are identified. However, with the use of gloves and respirators (PPE) the MOEs for most exposure scenarios are above the target MOEs. However, it should be noted that the Agency can not require the use of gloves or respirators (PPE) on in-can paint preservative labels.

As previously mentioned, the calculated dermal MOEs for many of the exposure scenarios are above the ST and IT target MOEs with the use of gloves (PPE). However, the following occupational handler exposure scenario indicates dermal risks of concern even with the use of gloves (PPE):

- Rubber & Plastics Preservation: Open Pour Wettable Powder
(IT Dermal MOE w/ gloves = 53)

The IT dermal MOE for paint preservation via open pour wettable powder is 83 with the use of gloves. However, because the Agency uses conservative assessment methods and the MOE of 83 is very close to the target of 100, the Agency believes that there are no risks of concern of this use pattern.

For the application of paint via airless sprayer and brush/roller two dermal exposure scenarios indicate risks of concern. It should be noted, that the Agency can not require the use of gloves (PPE) on in-can paint preservative labels. The following application use scenarios indicate dermal risks of concern for occupational handlers:

- Painting: Airless Sprayer
(Dermal MOE = 29 ST)
- Painting: Brush/Roller
(Dermal MOE = 62 ST)

For inhalation exposure, the target MOE for identifying risks of concern is 100 for short- and intermediate-term exposure durations. The target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However, if the inhalation MOE is greater than 100 but less than 1,000, inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation (use of oral toxicity data to set an inhalation endpoint) does not underestimate inhalation exposure risk.

All of the inhalation materials preservation scenarios assessed indicate no risks of concern for occupational handlers (MOEs above 100) with the use of a respirator (PPE) and, therefore, are not of concern.

For application of in-can paint, PPE (respirator or gloves) can not be required. The following occupational application inhalation exposure scenario has an MOE below the target of 100 and, therefore, is of concern:

- Painting: Airless Sprayer
(Inhalation MOE = 67)

Confirmatory inhalation toxicity data are needed because several of the inhalation MOEs are below the high-end target MOE of 1,000. For further information regarding the short- and intermediate-term risks associated with occupational handlers, refer to Table 14 below.

Table #14. Short- and Intermediate-Term Risks Associated with Occupational Handlers

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)			% ai or lb ai/gal.(% ai per wt)	Use Informtion	Absorbed Daily Dose (mg/kg/day) ^c		Inhal. ST/IT	Baseline Dermal (Target MOE = 100 ST /IT) ^{a,d}		PPE-Gloves Dermal (Target MOE = 100 ST and 100 IT) ^{b,d}		Inhalation(Target MOE = 100 ST/IT) ^d	
		Baseline Dermal ^a	PPE-Gloves Dermal ^b	Inhalation			Dermal ST/IT	PPE-Gloves Dermal ST/IT ^b		ST	IT	ST	IT	Baseline	PPE
Preservation of Paint	Liquid Pour	NA	0.135	0.00346	40%	50 lb prod./day (Registrant Estimate)	NA	3.9E-3	9.9E-4	NA	NA	1037	519	2023	NA
					0.05 lb ai/gal	2000 gallon (250 lb prod/day)		1.9E-2	4.9E-3	NA	NA	207	104	405	NA
	Open Pour Wettable Powder	NA	0.17	0.0434	95%	50 lb prod/day (Registrant Estimate)	NA	4.9E-3	1.2E-2	NA	NA	824	412	161	NA
					0.049 lb ai/gal	2000 gallon (250 lb prod/day)		2.4E-2	6.1E-2	NA	NA	167	83	33	163
	Liquid Pump	NA	0.00629	0.000403	0.05 lb ai/gal	20000 gallon (2,500 lb prod/day)	NA	9.0E-3	5.8E-3	NA	NA	445	223	347	1737
	Water Soluble Bags	NA	0.0098	0.00024	0.049 lb ai/gal	20000 gallon (2,500 lb prod/day)		1.4E-2	3.4E-3	NA	NA	289	145	590	2951
Application of Paint by a Professional Painter	Brush/ Roller	180	24	0.28	0.05 lb ai/gal	5 gal	6.4E-2	NA	1.0E-03	62	31	NA	NA	2000	NA
	Airless Sprayer	38	14	0.83	0.05 lb ai/gal	50 gal	0.14	NA	0.03	29	15	NA	NA	67	NA
Preservation of Adhesives and Caulks	Liquid Pour	NA	0.135	0.00346	40%	50 lb prod/day (Registrant Estimate)	NA	3.9E-3	9.9E-4	NA	NA	1037	519	2023	NA
					0.29% ai by wt.	10000 lb (72 lb prod/day)		5.6E-3	1.4E-3			720	360	1405	

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)			% ai or lb ai/gal.(% ai per wt)	Use Informtion	Absorbed Daily Dose (mg/kg/day) ^c		Inhal. ST/IT	Baseline Dermal (Target MOE = 100 ST /IT) ^{a,d}		PPE-Gloves Dermal (Target MOE = 100 ST and 100 IT) ^{b,d}		Inhalation(Target MOE = 100 ST/IT) ^d	
		Baseline Dermal ^a	PPE-Gloves Dermal ^b	Inhalation			Dermal ST/IT	PPE-Gloves Dermal ST/IT ^b		ST	IT	ST	IT	Baseline	PPE
	Open Pour Wettable Powder	NA	0.17	0.0434	95%	20 lb prod/day (Registrant Estimate)		4.6E-3	1.2E-2	NA	NA	867	433	170	849
					0.30% ai per wt.	10000 lb (30 lb prod/day)		6.9E-3	1.8E-2			578	289	113	566
Preservation of Adhesives and Caulks	Liquid Pump	NA	0.00629	0.000403	0.30% ai per wt.	10000 lb (30 lb prod/day)	NA	2.6E-4	1.7E-4	NA	NA	15457	7728	12062	NA
	Water Soluble Bags	NA	0.0098	0.00024		10000 lb (30 lb prod/day)	NA	4E-4	9.8E-5	NA	NA	10025	5013	20468	NA
Preservation of Slurries	Liquid Pour	NA	0.135	0.00346	40%	50 lb prod/day (Registrant Estimate)	NA	3.9E-3	9.9E-4	NA	NA	1037	519	2023	NA
					0.15%	10000 lb (38 lb prod/day)	NA	2.9E-3	7.5E-4	NA	NA	1365	682	2662	NA
	Open Pour Wettable Powder	NA	0.17	0.0434	95%	20 lb prod/day (Registrant Estimate)	NA	4.6E-3	1.2E-2	NA	NA	867	433	170	849
					0.15% ai per wt.	10000 lb (15 lb prod/day)		3.6E-3	9.3E-3			1097	548	215	1074
	Liquid Pump	NA	0.00629	0.000403	0.15% ai per wt.	10000 lb (15 lb prod/day)	NA	1.4E-4	8.8E-5	NA	NA	29286	14643	22855	NA
	Water Soluble Bags	NA	0.0098	0.00024	0.15% ai per wt.	10000 lb (15 lb prod/day)		2.1E-4	5.1E-5	NA	NA	19023	9511	38838	NA
Preservation of Emulsions	Liquid Pour	NA	0.135	0.00346	40%	50 lb prod/day (Registrant Estimate)	NA	3.9E-3	9.9E-4	NA	NA	1037	519	2023	NA
					0.14% ai per wt.	10000 lb (38 lb prod/day)		2.7E-3	7.0E-4			1455	728	2839	
	Open Pour Wettable Powder	NA	0.17	0.0434	95%	20 lb prod/day (Registrant Estimate)	NA	4.6E-3	1.2E-2	NA	NA	867	433	170	849
					0.15%ai per wt.	10000 lb (15 lb prod/day)		3.6E-3	9.3E-3			1097	548	215	1074
	Liquid Pump	NA	0.00629	0.000403	0.15%ai per wt.	10000 lb (15 lb prod/day)	NA	1.3E-4	8.2E-5	NA	NA	31239	15619	24379	NA
	Water Soluble Bags	NA	0.0098	0.00024	0.15%ai per wt.	10000 lb (15 lb prod/day)	NA	2.1E-4	5.1E-5			19023	9511	38838	

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)			% ai or lb ai/gal.(% ai per wt)	Use Informtion	Absorbed Daily Dose (mg/kg/day) ^c		Inhal. ST/IT	Baseline Dermal (Target MOE = 100 ST /IT) ^{a,d}		PPE-Gloves Dermal (Target MOE = 100 ST and 100 IT) ^{b,d}		Inhalation(Target MOE = 100 ST/IT) ^d	
		Baseline Dermal ^a	PPE-Gloves Dermal ^b	Inhalation			Dermal ST/IT	PPE-Gloves Dermal ST/IT ^b		ST	IT	ST	IT	Baseline	PPE
Preservation of Rubber and Plastics	Liquid Pour	NA	0.135	0.00346	15	50 lb prod/day (Registrant Estimate)	NA	1.4E-3	3.7E-4	NA	NA	2765	1383	5395	NA
					0.264%ai per wt.	2,000 gallons or 20000 lb (300 lb prod/day)		1E-2	2.6E-3			393	196	766	
	Open Pour Wettable Powder	NA	0.17	0.0434	95%	20 lb prod/day (Registrant Estimate)	NA	3.7E-4	9.4E-4	NA	NA	1092	546	2130	NA
					0.78% ai per wt.	2,000 gallons or 20,000 lb (320 lb prod/day)		3.8E-2	9.6E-2			106	53	21	104

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)			% ai or lb ai/gal.	Lb product handled per day	Absorbed Daily Dose (mg/kg/day) ^c			Baseline Dermal (Target MOE = 100 ST /IT) ^{a,d}		PPE-Gloves Dermal (Target MOE = 100 ST and 100 IT) ^{b,d}		Inhalation(Target MOE = 100 ST/IT) ^d	
		Baseline Dermal ^a	PPE-Gloves Dermal ^b	Inhalation			Dermal ST/IT	PPE-Gloves Dermal ST/IT ^b	Inhal. ST/IT	ST	IT	ST	IT	Baseline	PPE
Preservation of Rubber and Plastics	Liquid Pump	NA	0.00629	0.000403	0.264%ai per wt.	20,000 gallons or 200,000 lb (3,000 lb prod/day)	NA	4.7E-3	3E-3	NA	NA	843	422	658	3290
	Water Soluble Bags	NA	0.0098	0.00024	0.78% ai per wt.	20,000 gallons or 200,000 lb (3,000 lb prod/day)	NA	2.2E-2	5.3E-3	NA	NA	184	92	376	1881
Preservation of Leather (Tanning Drum)	Liquid Pour	NA	0.135	0.00346	40%	11 lb prod/day (Registrant Estimate)	NA	8.5E-4	2.2E-4	NA	NA	4714	2357	9196	NA
					0.26%ai per wt.	10000 lb (172 lb prod/day)	NA	1.3E-2	3.4E-3	NA	NA	302	151	589	2947
	Open Pour Wettable Powder	NA	0.17	0.0434	95%	6 lb prod/day (Registrant Estimate)	NA	1.4E-3	3.5E-3	NA	NA	2890	1445	566	2830
					0.296%ai per wt.	10000 lb (78 lb prod/day)		1.9E-2	4.8E-2			214	107	42	210
Preservation of Leather (Tanning Drum)	Liquid Pump	NA	0.00629	0.000403	0.26%ai per wt.	10000 lb (172 lb prod/day)	NA	6.2E-4	4.0E-4	NA	NA	6485	3243	5061	NA
	Water Soluble Bags	NA	0.0098	0.00024	0.296%ai per wt	10000 lb (78 lb prod/day)	NA	1.1E-3	2.6E-04	NA	NA	3718	1859	7591	NA

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)			% ai or lb ai/gal.	Lb product handled per day	Absorbed Daily Dose (mg/kg/day) ^c			Baseline Dermal (Target MOE = 100 ST /IT) ^{a,d}		PPE-Gloves Dermal (Target MOE = 100 ST and 100 IT) ^{b,d}		Inhalation (Target MOE = 100 ST/IT) ^d	
		Baseline Dermal ^a	PPE-Gloves Dermal ^b	Inhalation			Dermal ST/IT	PPE-Gloves Dermal ST/IT ^b	Inhal. ST/IT	ST	IT	ST	IT	Baseline	PPE
Preservation of Textiles (Non-Clothing)	Liquid Pour	NA	0.135	0.00346	40%	50 lb prod/day (Registrant Estimate)	NA	3.90E-03	9.9E-04	NA	NA	1037	519	2023	NA
					0.0048 lb ai/lb dry weigh	10000 lb dry wt.		9.2E-3	2.3E-03			437	218	852	4259
	Open Pour Wettable Powder	NA	0.17	0.0434	95%	50 lb prod/day (Registrant Estimate)	NA	1.2E-02	2.9E-02	NA	NA	347	173	68	340
					0.005 lb ai/lb dry weigh	10000 lb dry wt.		1.2E-02	3.1E-02			329	165	65	323
Preservation of Textiles (Non-Clothing)	Liquid Pump	NA	0.00629	0.000403	0.0048 lb ai/lb dry weigh	10000 lb dry wt.	NA	4.3E-04	2.7E-04	NA	NA	9372	4686	7314	NA
	Water Soluble Bags	NA	0.0098	0.00024	0.005 lb ai/lb dry weigh	10000 lb dry wt.	NA	7E-04	1.7E-04	NA	NA	5714	2857	11667	NA
Preservation of Paper	Liquid Pump	NA	0.00629	0.000403	0.768 lb ai/ton	500 tons	NA	3.5E-3	2.2E-3	NA	NA	1159	580	905	4523
	Water Soluble Bags		0.0098	0.00024	0.775 lb ai/ton			5.4E-3	1.3E-3			737	369	1505	NA
Application of Wood Preservative by professionals	Brush/ Roller	180	24	0.28	2.1E-4 Lb ai/sq ft	300 sq ft	1.6E-2	2.2E-3	2.5E-4	245	123	1841	920	7888	NA
	Airless Sprayer	38	14	0.83			3.4E-3	1.3E-3	7.5E-4	1163	581	2661	1578	2661	NA

ST = short-term, IT = intermediate-term, N/A= Not applicable. For material preservative, no appropriate surrogate data was found for ungloved conditions.

a Baseline Dermal: Long-sleeve shirt, long pants, no gloves.

b PPE Dermal with gloves: baseline dermal plus chemical-resistant gloves.

c Absorbed Daily dose (mg/kg/day) = [unit exposure (mg/lb ai) * absorption (1.0 for ST/IT inhalation and ST dermal, 0.10 for ST/IT dermal) * application rate * quantity treated / Body weight (70 kg).

d MOE = NOAEL (mg/kg/day) / Absorbed Daily Dose [Where short-term NOAEL = 4 mg/kg/day for dermal and intermediate-term LOAEL = 2 mg/kg/day for IT dermal and inhalation exposures].

NC = Not conducted: IT exposures were not assessed for professional painters because it was assumed that professional painters applying paint or wood preservatives will not use Diiodomethyl-p-tolylsulfone preserved paint on a continuous basis.

Wood Preservation & Application- Handler Risk Summary

Occupational handler exposure to diiodomethyl p-tolyl sulfone may occur as a result of wood preservation and wood preservative application. The calculated dermal exposure MOEs for wood preservation were all above the target MOE of 100 and, therefore, are not of concern.

For inhalation exposure the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for inhalation toxicity data is 1,000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However if the inhalation MOE is greater than 100 but less than 1,000, inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation (use of oral toxicity data to set an inhalation endpoint) does not underestimate inhalation exposure risk. All of the inhalation scenarios assessed were not of concern (MOEs greater than 100) for occupational wood preservation. However, one of the inhalation scenarios has an MOE below 1,000 and, therefore, triggers the need for an inhalation toxicity study to confirm that there are no inhalation risks of concern. The following use scenario triggers the need for confirmatory inhalation toxicity data:

- Blender/ Spray Operator: CMA Liquid Pump
(Inhalation MOE = 203 @ 0.96% application rate; MOE = 403 @ 0.48% application rate)

For further information regarding the short- and intermediate-term risks and MOEs for wood preservative blender/spray operators, chemical operators, and diptank operators refer to Tables 15, 16 and 17.

Table #15. Short- and Intermediate-term Exposures and MOEs for Wood Preservative Blender/spray Operators

	CMA Dermal UE (mg/lb ai)	CMA Inhal UE (mg/lb ai)	App Rate (% ai)	Quantity Treated (lb/day)	Daily Dermal Dose ^a (mg/kg/day)	Daily Inhal. Dose ^a (mg/kg/day)	Dermal MOE ^b		Inhalation MOE ^b
							ST	IT	
CMA Liquid Pump	0.00629	0.000403	0.96%	178,000	0.015	0.0098	261	130	203
			0.48%		0.0077	0.0050	516	258	403

a Daily Dose = UE (mg/lb ai) x App Rate (% ai) x Quantity treated (lb/day) x absorption factor (ST/IT dermal = 0.10, not necessary for inhalation)/ BW (70 kg)

b MOE = NOAEL (mg/kg/day)/ Daily dose [Where short-term NOAEL = 4 mg/kg/day for dermal and the NOAEL for inhalation exposures and intermediate-term = 2 mg/kg/day for dermal and inhalation exposures].

Table #16. Short- and Intermediate-term Exposures and MOEs for Wood Preservative Chemical Operators

Exposure Scenario ^a (number of volunteers)	Dermal UE ^b (mg/day)	Inhalation UE ^b (mg/day)	Conversion Ratio ^c	Absorbed Daily Doses ^d (mg/kg/day)		MOE=100	MOE=100		
				Dermal	Inhalation	Dermal		Inhalation	
						ST	IT	ST /IT/LT	
Chemical Operator (n=11)	9.81	0.0281	0.32	0.0045	0.00013	892	446	15,569	

ST = Short-term duration; IT = Intermediate-term duration; and LT = long-term duration

a. The exposure scenario represents a worker wearing short sleeve shirts, cotton work trousers, and cotton glove dosimeter gloves under chemical resistant gloves. Volunteers were grouped according to tasks they conducted at the mill.

- b. Dermal and inhalation unit exposures are from Bestari et al (1999). Refer to Table A-1 in Appendix A for the calculation of the dermal and inhalation exposures. Inhalation exposures (mg/day) were calculated using the following equation: air concentration (ug/m³) x inhalation rate (1.0 m³/hr) x sample duration (8 hr/day) x unit conversion (1 mg/1000 ug). The inhalation rate is from USEPA, 1997a.
- c. Conversion Ratio = 0.95% ai solution/3.0% ai solution
- d. Absorbed Daily Dose (mg/kg/day) = exposure (mg/day) * conversion ratio (0.6) * absorption factor (0.12 for ST/IT dermal and 1.0 for inhalation) / body weight (70 kg).
- e. MOE = NOAEL (mg/kg/day) / Daily Dose [Where ST NOAEL = 4 mg/kg/day for dermal exposures, and IT LOAEL = 2 mg/kg/day for IT dermal and all durations of inhalation]. Target MOE is 100 for ST dermal and 300 for IT dermal and inhalation exposures.

Table #17. Short- and Intermediate-term Exposures and MOEs for Wood Preservative Diptank Operators

Exposure Scenario ^a (number of replicates))	Dermal Unit Exposure ^b (mg DDAC/1% solution)	Inhalation Unit Exposure ^b (mg DDAC/1% solution)	Application Rate (% a.i. in solution/day) ^c	Absorbed Daily Doses ^d (mg/kg/day)		MOEs ^e (target MOE = 100)		
				Dermal	Inhalation	Dermal		Inhalation
						ST	IT	ST / IT
Chemical Operator Dipping with Gloves (n=11)	2.99	0.046	0.96	0.0041	0.00063	975	488	3170

ST = Short-term duration; IT =Intermediate-term duration; and LT = long-term.

- a. The exposure scenario represents a worker wearing long-sleeved shirts, cotton work trousers, and gloves. Gloves were worn only when near chemicals, not when operating the diptank.
- b. Dermal and inhalation unit exposures are from the DDAC study (MRID 455243-04). Refer to Table A-2 in Appendix A for the dermal and inhalation unit exposure calculations. Inhalation exposure (mg) was calculated using the following equation: Air concentration (mg/m³) x Inhalation rate (1.0 m³/hr) x Sample Duration (8 hr). The inhalation rate is from USEPA, 1997a.
- c. The application rate is 0.96%a.i. in treatment solution (formulated product is applied at a rate of 48.45% of the weight of the wood treated, and the product contains 2% a.i.)
- d. Absorbed Daily Dose (mg/kg/day) = unit exposure (mg/1% ai solution) * percent active ingredient in solution absorption factor (12% for dermal ST/IT, and 100% for all other exposures/durations) / body weight (70 kg).
- e. MOE = NOAEL (mg/kg/day) / Daily Dose [Where ST NOAEL = 4 mg/kg/day for dermal and the IT LOAEL = 2 mg/kg/day for dermal and all inhalation durations]. Target MOE is 100 for ST dermal and 300 for IT dermal and inhalation exposures.

d. Occupational Post-application Risk Summary

Occupational handlers may have post-application exposure to diiodomethyl p-tolyl sulfone by handling treated wood. Diiodomethyl p-tolyl sulfone products that are intended to preserve wood (pressure and non-pressure treatment) are used for control of mildew, sapstain, and wood rotting organisms. Diiodomethyl p-tolyl sulfone can be incorporated into appropriate vehicles to protect wood from stain and decay (for formulating uses only). Diiodomethyl p-tolyl sulfone can also be used for control of mildew, sapstain, and wood rotting organisms at wood treatment facilities; or it can be incorporated into other registered wood preservatives for typical uses such as building lumber, furniture, frames, decking, fences, shingles, and siding logs and poles. Occupational post-application risks are assumed to be negligible for all diiodomethyl p-tolyl sulfone use patterns with the exception of the wood preservative scenarios.

Chemical Operators/ Graders/ Millwrights/ Trim Saw Operators/ Clean-up Crews

Post-application exposures to chemical operators, graders, millwrights, trim saw operators, and clean-up crews were assessed using surrogate data from the DDAC study (Bestari et al., 1999). This study examined individuals' exposure to DDAC while working with anti-sapstain chemicals and performing routine tasks at 11 sawmills/planar mills in Canada. Dermal and inhalation exposure monitoring data were gathered for each job function of interest using dosimeters and personal sampling tubes. These sample media were then analyzed for DDAC, and the results were reported in terms of mg DDAC exposure per person per day. The study reported average daily exposures for workers in various categories. Exposure data for individuals performing the same job functions were averaged together to determine job specific averages. Total exposures from 2 trim saw workers, 13 grader workers, 11 chemical operators, 3 millwrights, and 6 clean-up staff were used.

To determine diiodomethyl p-tolyl sulfone exposures, the average DDAC exposures measured on individuals (in terms of total mg DDAC) were multiplied by a modification factor of 0.32 to account for the difference in percent active ingredient between diiodomethyl p-tolyl sulfone and DDAC (48% diiodomethyl p-tolyl sulfone in the wood preservative product versus 80% DDAC in the comparative wood preservative product). The pounds (lb) of active ingredient handled by each person or the percent (%) active ingredient in the treatment solution were not provided for these worker functions.

Table 18 provides the short-, intermediate-, and long-term doses and MOEs for graders, millwrights, clean-up crews, and trim saw operators. For all but one of the worker functions, the post-application dermal MOEs are above the target MOE of 100 for ST/ IT durations assessed. The following post-application worker function has an IT dermal MOE below 100 and, therefore, is of concern:

- Clean-Up: Wood Preservation
(IT Dermal MOE = 79)

For all worker functions, the inhalation MOEs are above the target MOE of 100 and, therefore, are not of concern. However, one of the inhalation scenarios has an MOE below the high-end target MOE of 1,000 and, therefore, triggers the need for an inhalation toxicity study to confirm that there are no inhalation risks of concern. The following use scenario triggers the need for confirmatory inhalation toxicity data:

- Clean-Up: Wood Preservation
(Inhalation MOE = 729)

Table #18. Short- and Intermediate-term Post-application Occupational Exposures and MOEs for Wood Preservative Grader, Trim Saw, Millwright and Clean-Up Staff

Exposure Scenario ^a (number of volunteers)	Dermal UE ^b (mg/day)	Inhalation UE ^b (mg/day)	Conversion Ratio ^c	Absorbed Daily Doses ^d (mg/kg/day)		MOE=100	MOE=100		
				Dermal	Inhalation	Dermal		Inhalation	
						ST	IT	ST /IT/LT	
Grader (n=13)	3.13	0.0295	0.32	0.0014	0.00013	2796	1398	14,831	
Trim Saw (n=2)	1.38	0.061	0.32	0.00063	0.00027	6341	3170	7,172	
Millwright (n=3)	12.8	0.057	0.32	0.0059	0.00026	683	342	7,675	
Clean-Up (n=6)	55.3	0.60	0.32	0.026	0.0027	158	79	729	

ST = Short-term duration; IT = Intermediate-term duration; and LT = long-term duration

a. The exposure scenario represents a worker wearing short sleeve shirts, cotton work trousers, and cotton glove dosimeter gloves under chemical resistant gloves. Volunteers were grouped according to tasks they conducted at the mill.

b. Dermal and inhalation unit exposures are from Bestari et al (1999). Refer to Table A-1 in Appendix A for the calculation of the dermal and inhalation exposures. Inhalation exposures (mg/day) were calculated using the following equation: air concentration (ug/m³) x inhalation rate (1.0 m³/hr) x sample duration (8 hr/day) x unit conversion (1 mg/1000 ug). The inhalation rate is from USEPA, 1997a.

c. Conversion Ratio = 0.95% ai solution/3.0% ai solution

d. Absorbed Daily Dose (mg/kg/day) = exposure (mg/day) * conversion ratio (0.6) * absorption factor (0.12 for ST/IT dermal and 1.0 for inhalation) / body weight (70 kg).

e. MOE = NOAEL (mg/kg/day) / Daily Dose [Where ST NOAEL = 4 mg/kg/day for dermal exposures, and IT LOAEL = 2 mg/kg/day for IT dermal and all durations of inhalation]. Target MOE is 100 for ST dermal and 300 for IT dermal and inhalation exposures.

Construction Workers

Not enough data exists to estimate the amount of exposure associated with construction workers who install treated wood. In particular, values for the transfer coefficient associated with a construction worker handling the wood could not be determined. It is believed that the construction worker using a trim saw will have larger dermal and inhalation exposures than the installer, due to the amount of sawdust generated and the greater amount of hand contact that would be necessary to handle the wood when using a saw compared to installing the wood. Because the dermal and inhalation MOEs are well above the target of 100 for trim saw operators and handler exposure is expected to be greater for trim saw operation, risks of concern are not anticipated for construction workers installing treated wood.

Pressure Treatment Scenarios (Handler & Post-Application Exposure Scenarios)

Diiodomethyl p-tolyl sulfone wood preservatives may be used to treat wood and wood products using pressurized application methods, specifically empty-cell vacuum pressure techniques. Chemical-specific exposure data are not available to assess the potential pressure treatment exposure of diiodomethyl p-tolyl sulfone. Therefore, the assessment was based on surrogate chromated copper arsenate (CCA) data (ACC, 2002). Dermal and inhalation exposures for pressure treatment uses are derived from information in the exposure study sponsored by the American Chemistry Council (2002) entitled "Assessment of Potential Inhalation and Dermal

Exposure Associated with Pressure Treatment of Wood with Arsenical Wood Products” (ACC, 2002). In this study, a treatment solution of CCA was approximately 0.5 percent active ingredient. The CCA exposure monitoring study is considered a valid surrogate source of data for pressure treatment applications and was therefore used in estimating exposure to diiodomethyl p-tolyl sulfone.

The estimated dermal and inhalation handler and post-application exposures and risks for the diiodomethyl p-tolyl sulfone pressure treatment uses are presented in Table 19. Risks of concern have been identified for occupational handler treatment operators (TO) for IT dermal exposure. The following pressure treatment occupational handler scenario is of concern:

- Pressure Treatment Operator: Wood Preservation (IT Dermal MOE = 69)

The dermal and inhalation MOEs are all above the target of 100 for all occupational post-application pressure treatment job functions and therefore, are not of concern.

Table #19. Short-, Intermediate-, and Long-Term Exposures and MOEs for Pressure Treatment Handler & Post-Application Scenarios

Exposure Scenario ^a	Unit Exposure ^a (µg As/ppm)		Application Rate (% ai solution)	Absorbed Daily Doses ^b (mg/kg/day)		MOEs ^c		
	Dermal	Inhalation		Dermal	Inhalation	Dermal ST/IT Target = 100		Inhalation ST/IT/LT Target=100
						ST	IT	
Occupational Handler								
Treatment Operator (TO)	2.04	0.00257	1	0.029	3.67E-5	137	69	5.45E+4
Treatment Assistant (TA)	0.24	0.000802	1	0.0034	1.15E-5	1167	583	1.75E+5
Occupational Post-application								
All Job Functions (Tram setter, stacker operator, loader operator, supervisor, test borer, and tallyman)	0.74	0.00160	1	0.011	2.29E-5	378	189	8.75E+4

ST = Short-term duration; IT = Intermediate-term duration; and LT = long-term.

a. Unit exposure values are taken from CCA study as shown above and in Table 6.6.

b. Absorbed Daily Dose (mg/kg/day) = Unit Exposure (µg As/ppm) * [% Diiodomethyl-p-tolylsulfone in solution (1) * 10,000 (parts per million conversion)] * (0.001 mg/µg) * absorption factor (0.12 for dermal; 100% for inhalation) / Body weight (70 kg).

c. MOE = NOAEL (mg/kg/day) / Daily dose [Where ST (systemic) NOAEL = 4 mg/kg/day for dermal and IT LOAEL = 2 mg/kg/day for inhalation]. Target ST/IT MOE is 100 for dermal exposure, and 100 for inhalation exposure.

9. Human Incident Data

The Agency reviewed the following information for human poisoning incidents related to diiodomethyl p-tolyl sulfone use and discovered that no incidents have been reported: (1) OPP Incident Data System (IDS)- The Office of Pesticides 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 Telecommunications Network (NPTN)- NPTN 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) National Poison Control Centers (PCC) (1993-2002)- The Agency has received PCC data covering the years 1993-2002 for all pesticides. Most of the national PCCs participate in a national data collection system, the Toxic Exposure Surveillance System, which obtains data from about 65-70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings involving drugs, household products, pesticides, etc.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. Diiodomethyl p-tolyl sulfone is used as an above-ground wood preservative for control of mildew, sapstain, and wood-rotting organisms at wood treatment facilities. Diiodomethyl p-tolyl sulfone is also incorporated into other registered wood preservatives. Environmental exposure levels from wood preservative applications may be of concern for organisms exposed to leachate or runoff. Therefore, an ecological risk assessment was conducted for the wood preservative/treatment uses of diiodomethyl p-tolyl sulfone. All other diiodomethyl p-tolyl sulfone uses are considered to be indoor uses and to have minimal to no environmental exposure potential following use. Therefore, the material preservative uses were not assessed for ecological risk. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for diiodomethyl p-tolyl sulfone use sites and any associated uncertainties.

For a detailed discussion of all aspects of the environmental risk assessment, refer to the "Diiodomethyl p-tolyl sulfone. P.C. Code: 101002. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. Case 4009," dated April 29, 2008; the "Revised Environmental Hazards and Ecological Risk Assessment for the Diiodomethyl p-tolyl sulfone RED," dated March 12, 2008; and the "Environmental Fate Assessment of Diiodomethyl p-tolyl sulfone for the RED," dated March 26, 2008.

1. Environmental Fate and Transport

Diiodomethyl p-tolyl sulfone degrades by hydrolysis and metabolism to form dehalogenated and demethylated compounds. Diiodomethyl p-tolyl sulfone is stable to

hydrolysis at pH 5, but degrades at pH 7 and 9 to form MIMPTS (monoiodo-p-tolylsulfone), which only degrades slightly. Water solubility and vapor pressure increases as degradation continues, but volatility from water is negligible because of increasing solubility. Significant bioconcentration is not expected from parent diiodomethyl p-tolyl sulfone or the metabolites based on the low (<3) log K_{ow} (Log P). Release to water from treated soil and wood are significant routes of dissipation.

Acute exposure to parent diiodomethyl p-tolyl sulfone may occur, but chronic exposure is not likely. Parent half-lives range from 1.5-9.6 days in hydrolysis (pH 7-9) and in metabolism studies. Aqueous residues of parent diiodomethyl p-tolyl sulfone were higher than sediment residues for seven days in the anaerobic aquatic metabolism study (representing bottom sediment).

Chronic exposure to aquatic organisms is likely to occur from MIMPTS (parent minus one iodo group) and from MPTS (parent minus both iodo groups). MIMPTS was the terminal residue in hydrolysis and aqueous photodegradation studies. MIMPTS was stable in non-irradiated soil but degraded with a half-life of 12.5 day in the irradiated samples. In aerobic soil (the top layer of non-flooded soil), the half-lives of MIMPTS and MPTS were 32 and 53-173 days, respectively. In anaerobic soil (the second layer of soil), MIMPTS was a major degradate with a half-life of 21 days and was found predominantly in water. MPTS reached 81% by the end of the study and was primarily found in water. Anaerobic aquatic metabolism (representing bottom sediment) degrades MIMPTS with a total system half-life of 11 days. MPTS was the terminal metabolite and increased to 95% by 4-6 months. Aqueous residues were greater than sediment residues for MIMPTS and MPTS for 180 and 60 days, respectively.

In addition, diiodomethyl p-tolyl sulfone degrades to residues with greater polarity and water solubility than itself. The water solubility of the parent, MIMPTS, and MPTS from the EPI-Suite model are 0.8, 175, and 1750 mg/l, respectively. Therefore, aqueous residues of diiodomethyl p-tolyl sulfone metabolites will likely be present for extended periods of time from treated wood on land.

a. Bioaccumulation in Aquatic Organisms

Significant bioconcentration is not expected from the parent diiodomethyl p-tolyl sulfone or the metabolites based on the low (<3) log K_{ow} (Log P). Release to water from treated soil and wood are significant routes of dissipation. The Log K_{ow} (Log P) of diiodomethyl p-tolyl sulfone is 2.66. The estimated Log K_{ow} values for MIMPTS, MPTS, and PTSA are 2.2, 1.1, and 0.56, respectively.

2. Ecological Risk

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

a. Environmental Toxicity

Terrestrial Animals

Toxicity to Birds, Acute & Dietary

Available data indicate that diiodomethyl p-tolyl sulfone is practically non-toxic to birds when ingested on an acute oral and dietary basis. Therefore, an avian precautionary statement is not required on product labels.

Toxicity to Mammals, Acute

Based on the results of mammalian studies conducted to meet human toxicity data requirements, diiodomethyl p-tolyl sulfone exhibits low acute oral and acute dermal toxicity (Toxicity Category IV), and high acute inhalation toxicity (Toxicity Category II). Diiodomethyl p-tolyl sulfone is classified as an eye corrosive (Toxicity Category I). For dermal irritation, diiodomethyl p-tolyl sulfone is a low irritant (Toxicity Category IV) and is not classified as a dermal sensitizer.

Aquatic Organisms

Toxicity to Freshwater Fish; Freshwater Invertebrates; Estuarine & Marine Organisms, Acute

On an acute basis, diiodomethyl p-tolyl sulfone is highly to very highly toxic to freshwater fish and freshwater invertebrates.

Acute toxicity testing with estuarine marine organisms using the TGAI is required when an end-use product is intended for direct application to the marine/estuarine environment, or the active ingredient is expected to reach this environment in significant concentrations because of its expected use and mobility. There are currently no acceptable acute toxicity data for estuarine/marine fish (OPPTS 850.1075), estuarine marine shrimp (OPPTS 850.1035), or estuarine/marine mollusk (OPPTS 850.1025) for diiodomethyl p-tolyl sulfone. These data are required to support the wood preservative uses of diiodomethyl p-tolyl sulfone. Such data will allow the Agency to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps. Also, this data may remove uncertainties and may result in more accurate exposure estimations.

Toxicity to Aquatic Organisms, Chronic

Chronic toxicity data [(OPPTS 850.1400) Fish Early Life Stage; and (OPPTS 850.1300) Aquatic Invertebrate Life Cycle] are required for antimicrobial pesticides when certain conditions apply. For diiodomethyl p-tolyl sulfone, these conditions include acute toxicity to freshwater organisms and solubility and persistence of the major degradates. No chronic aquatic organism data are available for diiodomethyl p-tolyl sulfone. Chronic testing is required for both the freshwater fish and freshwater invertebrate. The preferred test material is the major

degradate, MIMPTS (parent minus one iodo group), and the preferred freshwater test species are the rainbow trout and *Daphnia magna*. Such data will allow the Agency to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps. Also, this data may remove uncertainties and may result in more accurate exposure estimations.

Toxicity to Aquatic Plants

The use of diiodomethyl p-tolyl sulfone as a wood treatment may result in chemical leachate from treated wood into the aquatic environment. As a result, aquatic plant toxicity data are required to assess this risk. No aquatic plant toxicity data are available for diiodomethyl p-tolyl sulfone. Therefore, the following data are required to fulfill aquatic plant toxicity data gaps: (1) freshwater diatom, *Navicula pelliculosa* (OPPTS 850.5400); (2) marine diatom, *Skeletonema costatum* (OPPTS 850.5400); (3) bluegreen cyanobacteria, *Anabaena flos-aquae* (OPPTS 850.5400); (4) freshwater green alga, *Selenastrum capricornutum* (OPPTS 850.5400); (5) freshwater floating macrophyte duckweed, *Lemna gibba* (OPPTS 850.4400); (6) freshwater rooted macrophyte rice seedling emergence, *Oryza sativa* (OPPTS 850.4225); (7) freshwater rooted macrophyte rice vegetative vigor (OPPTS 850.4250). These data are conditionally required to fulfill the aquatic plant toxicity data gaps for diiodomethyl p-tolyl sulfone, because aquatic plants may be exposed to diiodomethyl p-tolyl sulfone as a result of the wood preservative applications. This data may remove uncertainties and may result in more accurate exposure estimations. However, it should be noted that these data will not be required if appropriate label language is added to product labels that prohibits the use of pre-treated wood in structures located in surface waters (e.g., pilings) and prohibits topical application of diiodomethyl p-tolyl sulfone (e.g., brush on) to existing structures located or to be placed in surface waters (e.g., docks).

A summary of the submitted acute ecological, chronic aquatic organism, and aquatic plant toxicity data are provided in Tables 20, 21 and 22.

Table #20. Acute Ecological Toxicity

Species	Chemical	% Active Ingredient (AI)		Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID)
Birds (Acute Oral Toxicity & Dietary Toxicity)						
Bobwhite quail (<i>Colinus virginianus</i>)	Diiodomethyl p-tolyl sulfone (Acute Oral)	95%	LD ₅₀ > 2000 (mg ai/kg bw)	Practically Non-Toxic	Yes (core)	123643
	Diiodomethyl p-tolyl sulfone (Dietary)	95%	LD ₅₀ = 5620 (ppm)	Practically Non-Toxic	Yes (core)	123642
Mallard duck (<i>Anas platyrhynchos</i>)	Diiodomethyl p-tolyl sulfone (Dietary)	95%	LD ₅₀ = 5620 (ppm)	Practically Non-Toxic	Yes (core)	124488
Freshwater Fish (Acute Toxicity)						
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Diiodomethyl p- tolyl sulfone	97.7%	96-h LC ₅₀ = 66.7 (µg ai/L)	Very highly toxic	Supplemental	47234001
	Diiodomethyl p- tolyl sulfone	95%	96-h LC ₅₀ = 130 (µg ai/L)	Highly toxic	Yes (core)	149730
Bluegill sunfish (<i>Lepomis macrochirus</i>)	Diiodomethyl p- tolyl sulfone	95%	96-h LC ₅₀ = 750 (µg ai/L)	Highly toxic	Yes (core)	149731
Freshwater Invertebrates (Acute Toxicity)						
Waterflea (<i>Daphnia magna</i>)	Diiodomethyl p- tolyl sulfone	97.7%	48-h EC ₅₀ = 279 (µg ai/L)	Highly toxic	Yes (core)	47234002
	Diiodomethyl p- tolyl sulfone	95%	48-h EC ₅₀ = 7,400 (µg ai/L) ⁴	Moderately Toxic	Yes (core)	149729
	Diiodomethyl p- tolyl sulfone	95%	48-h EC ₅₀ = 71 (µg ai/L) ⁵	Very Highly Toxic	Supplemental	123644
Estuarine/Marine Organisms (Acute Toxicity)						
No data are currently available.						

⁴ The reported LC50 of 8 ppm in the Data Evaluation Report has been readjusted to an EC50, based on immobility of test daphnids reported at the 10 ppm test concentration.

⁵ Daphnids were entrapped at the air-water interface in all test concentrations; the presence of the toxicant at the solution surface, and the resulting entrapment of the test organisms, likely influenced the incidence of daphnid mortality.

Table #21. Chronic Aquatic Organisms Toxicity

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Aquatic Organisms (Chronic)				
No data are currently available.				

Table #22. Aquatic Plant Toxicity

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Aquatic Plants				
No data are currently available.				

b. Ecological Exposure and Risk

For the ecological exposure and risk assessment, the Agency has evaluated diiodomethyl p-tolyl sulfone wood preservative use scenarios. Wood preservative uses are considered to be “outdoor uses,” which are considered during reregistration. As discussed earlier, all other diiodomethyl p-tolyl sulfone uses are considered to be indoor uses and to have minimal to no environmental exposure potential following use.

The EPA performed an environmental risk assessment using estimated environmental concentrations (EECs) for diiodomethyl p-tolyl sulfone, which were developed from various models. EECs were modeled for antisapstain treatment and for wood treated by pressurized spray. Examples of treated wood products include wood houses, fences, decks, and transmission poles. The Agency does not believe that treated wood will be placed in surface waters (e.g., pilings) nor will topical application (e.g., brush-on) be made to wood (e.g., docks) located in water bodies. However, a label statement prohibiting such use needs to be added to product labels with wood preservative uses to limit these exposures. Provided that this label change is made, the data requirements discussed earlier will change as well.

Antisapstain Wood Preservative Use

To assess the use of diiodomethyl p-tolyl sulfone as an antisapstain treatment, storm water runoff concentrations of diiodomethyl p-tolyl sulfone were estimated for a hypothetical lumber yard where diiodomethyl p-tolyl sulfone is applied as an antisapstain (wood preservative) treatment. The methodology is based on a screening-level model to determine runoff concentrations of pesticides from antisapstain facilities in British Columbia, Canada (Krahn and Straub 1990). The concentration of diiodomethyl p-tolyl sulfone in runoff was calculated by dividing its concentration in leachate by a storm water dilution factor. For example, with the

dilution factor of 15, diiodomethyl p-tolyl sulfone leachate entering the storm drain is assumed to be diluted with uncontaminated runoff water at a 1:15 ratio. This dilution factor value is based on measurements of runoff in storm drains at facilities using antisapstain chemicals in British Columbia. The dilution factor ratios of 1:6 and 1:23 were used by Krahn and Straub (1990) to represent a “general industry wide” range of predicted runoff concentrations. For further information on the calculations used to derive these estimations as well as the uncertainties and limitations of the calculations, please refer to the “Revised Environmental Hazards and Ecological Risk Assessment for the Diiodomethyl p-tolyl sulfone RED,” dated March 12, 2008.

Other Wood Preservative Uses

EECs resulting from leaching of diiodomethyl p-tolyl sulfone from treated lumber into soil and surface waters were calculated for six uses including transmission poles, fence posts, fences, deck posts, decks, and houses. Use scenarios were evaluated using an estimate of the maximum cumulative aqueous release of diiodomethyl p-tolyl sulfone from a treated wood over a 14-day period. The methodology for this analysis is based on an environmental risk assessment previously prepared by the Rohm and Haas Company (2006) for 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone (DCOIT). In this methodology, leaching of diiodomethyl p-tolyl sulfone from treated wood surfaces is modeled to estimate soil loadings and concentrations. Soil concentrations and other input data were then used with EPA’s Express model EXAMS-PRZM Exposure Simulation Shell (version 1.03.02) to estimate concentrations in surface water. For further information on the calculations used to derive these estimations as well as the uncertainties and limitations of the calculations, please refer to the “Revised Environmental Hazards and Ecological Risk Assessment for the Diiodomethyl p-tolyl sulfone RED,” dated March 12, 2008.

Terrestrial Risk Assessment

Risk Assessment of Birds & Mammals, Acute

Minimal acute risk to birds and mammals is presumed for all registered uses of diiodomethyl p-tolyl sulfone because available data indicate that it is practically nontoxic to birds and mammals. Based on available avian toxicity data for diiodomethyl p-tolyl sulfone, the various wood treatments are not expected to be acutely toxic to avian & mammalian species.

Aquatic Risk Assessment

Risk Assessment of Freshwater Fish; Freshwater Invertebrates; Estuarine & Marine Organisms, Acute

To develop risk quotients (RQs), the estimated environmental concentrations (EECs) determined by modeling were compared to the most sensitive endpoint for each taxa. Acute LOCs (0.5) were not exceeded for non-listed freshwater fish or non-listed freshwater aquatic invertebrates for any scenario. However, freshwater fish and freshwater aquatic invertebrate LOCs were exceeded for listed (e.g., endangered and threatened) species for all three dilution-rate scenarios from antisapstain use.

There are currently no acceptable acute toxicity data for estuarine/marine fish (OPPTS 850.1075), estuarine marine shrimp (OPPTS 850.1035), or estuarine/marine mollusk (OPPTS 850.1025) for diiodomethyl p-tolyl sulfone. Therefore, the acute aquatic estuarine/marine species assessment is incomplete due to lack of toxicity data. These data are required to support the wood preservative uses of diiodomethyl p-tolyl sulfone. Such data will allow the Agency to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps. Also, this data may remove uncertainties and may result in more accurate estimates. However, it should be noted that these data requirements will be waived and not needed if the appropriate antisapstain label statement is added to the labels, and if all product labels are updated to include the appropriate label language, which prohibits the use of pre-treated wood in structures located in surface waters (e.g., pilings) and prohibits topical application of diiodomethyl p-tolyl sulfone (e.g., brush on) to existing structures located or to be placed in surface waters (e.g., docks). Such language will limit the possibility for diiodomethyl p-tolyl sulfone to contact all aquatic organisms, mitigating possible acute and chronic risks to aquatic organisms.

Risk Assessment of Aquatic Organisms, Chronic

The chronic aquatic toxicity assessment for estuarine/marine species could not be assessed due to lack of data. No chronic aquatic organism data [(OPPTS 850.1400) Fish Early Life Stage; and (OPPTS 850.1300) Aquatic Invertebrate Life Cycle] are available for diiodomethyl p-tolyl sulfone. The need for chronic freshwater fish and invertebrate studies are triggered based on acute toxicity. However, there are no acceptable chronic toxicity studies available for aquatic organisms. Chronic data are required for both the freshwater fish and freshwater invertebrate to fulfill current data guideline requirements for diiodomethyl p-tolyl sulfone. The preferred test material is the major degradate, MIMPTS (parent minus one iodo group), and the preferred freshwater test species are the rainbow trout and *Daphnia magna*. Such data will allow the Agency to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps. Also, this data may remove uncertainties and may result in more accurate estimates. However, it should be noted that these data requirements will be waived and not needed if the appropriate antisapstain label statement is added to the labels, and if all product labels are updated to include the appropriate label language, which prohibits the use of pre-treated wood in structures located in surface waters (e.g., pilings) and prohibits topical application of diiodomethyl p-tolyl sulfone (e.g., brush on) to existing structures located or to be placed in surface waters (e.g., docks). Such language will limit the possibility for diiodomethyl p-tolyl sulfone to contact all aquatic organisms, mitigating possible acute and chronic risks to aquatic organisms.

Risk Assessment of Aquatic Plants

An aquatic plants toxicity assessment could not be conducted due to lack of data. The use of diiodomethyl p-tolyl sulfone as a wood treatment may result in chemical leachate from treated wood into the aquatic environment. As a result, aquatic plant toxicity data are required to assess this risk. However, no aquatic plant toxicity data are available for diiodomethyl p-tolyl

sulfone. Therefore, the following data are required to fulfill aquatic plant toxicity data gaps: (1) freshwater diatom, *Navicula pelliculosa* (OPPTS 850.5400); (2) marine diatom, *Skeletonema costatum* (OPPTS 850.5400); (3) bluegreen cyanobacteria, *Anabaena flos-aquae* (OPPTS 850.5400); (4) freshwater green alga, *Selenastrum capricornutum* (OPPTS 850.5400); (5) freshwater floating macrophyte duckweed, *Lemna gibba* (OPPTS 850.4400); (6) freshwater rooted macrophyte rice seedling emergence, *Oryza sativa* (OPPTS 850.4225); (7) freshwater rooted macrophyte rice vegetative vigor (OPPTS 850.4250). This data will allow the Agency to conduct and complete an ecological assessment for aquatic plants, which could not be assessed as a result of data gaps. However, it should be noted that these data requirements will be waived and not needed if the appropriate antisapstain label statement is added to the labels, and if all product labels are updated to include the appropriate label language, which prohibits the use of pre-treated wood in structures located in surface waters (e.g., pilings) and prohibits topical application of diiodomethyl p-tolyl sulfone (e.g., brush on) to existing structures located or to be placed in surface waters (e.g., docks). Such language will limit the possibility for diiodomethyl p-tolyl sulfone to contact all aquatic organisms, mitigating possible acute and chronic risks to aquatic organisms.

Risk Assessment of 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 diiodomethyl p-tolyl sulfone 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.

Additional information regarding the diiodomethyl p-tolyl sulfone ecological assessment can be found in the "Diiodomethyl p-tolyl sulfone. P.C. Code: 101002. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. Case 4009," dated April 29, 2008; and the "Revised Environmental Hazards and Ecological Risk Assessment for the Diiodomethyl p-tolyl sulfone RED," dated March 12, 2008.

Please refer to Tables 23 and 24 for a comprehensive list of the identified ecological risk quotients for the antisapstain treatment and pressurized-spray treatment uses of diiodomethyl p-tolyl sulfone.

Table #23. Acute Risk Quotients and Risk Presumptions for Freshwater Fish

Use	EEC (µg ai/L)	Toxicity (µg ai/L)	Acute RQ	Acute LOCs Exceeded
Antisapstain treatment:				
Low dilution (1:6)	33	66.7	0.49	listed species
Typical dilution (1:15)	13	66.7	0.19	listed species
High dilution (1:23)	9	66.7	0.13	listed species
Pressurized-spray treatment:				
House	0.127	66.7	0.002	none
Deck	0.024	66.7	<0.001	none
Transmission pole	0.007	66.7	<0.001	none
Fence	0.002	66.7	<0.001	none
Deck Post	0.001	66.7	<0.001	none
Fence Post	<0.001	66.7	<0.001	none

Table #24. Acute Risk Quotients and Risk Presumptions for Freshwater Invertebrates

Use	EEC (µg ai/L)	Toxicity (µg ai/L)	Acute RQ	Acute LOCs exceeded
Antisapstain treatment:				
Low dilution (1:6)	33	71	0.46	listed species
Typical dilution (1:15)	13	71	0.18	listed species
High dilution (1:23)	9	71	0.12	listed species
Pressurized-spray treatment:				
House	0.127	71	0.002	none
Deck	0.024	71	<0.001	none
Transmission pole	0.007	71	<0.001	none

Use	EEC (µg ai/L)	Toxicity (µg ai/L)	Acute RQ	Acute LOCs exceeded
Fence	0.002	71	<0.001	none
Deck Post	0.001	71	<0.001	none
Fence Post	<0.001	71	<0.001	none

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 material preservative uses for diiodomethyl p-tolyl sulfone fall into this category.

The preliminary analysis for wood treatment uses indicates that there is a potential for diiodomethyl p-tolyl sulfone exposure of listed freshwater and aquatic invertebrate species. Since the models used to conduct the ecological risk assessment are only intended as screening-level models, and, as such, have inherent uncertainties and limitations, which may result in inaccurate exposure estimations, further refinement of the models and risk assessment are necessary before any regulatory action is taken regarding the wood treatment uses of diiodomethyl p-tolyl sulfone. A more refined assessment is warranted to include direct, indirect and habitat effects. Also, clear delineation of the action area associated with the proposed uses of diiodomethyl p-tolyl sulfone, and the best available information on the temporal and spatial co-location of listed species with respect to the action area should be included in a more refined assessment. Due to these circumstances, the Agency defers making an endangered species effect determination for the wood treatment uses of diiodomethyl p-tolyl sulfone until additional data and modeling refinements are available. At that time, the environmental exposure assessment for the wood treatment uses of diiodomethyl p-tolyl sulfone will be revised, and the risks to Listed Species will be considered. Registrants are responsible for amending all diiodomethyl p-tolyl sulfone antisapstain wood preservative product labels to incorporate the required antisapstain use label language. The antisapstain label statement is expected to decrease possible leaching risks associated with antisapstain use products.

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 diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone.

The Agency has completed its assessment of the residential, occupational and ecological risks associated with the use of pesticide products containing the active ingredient diiodomethyl p-tolyl sulfone. The Agency has determined that all diiodomethyl p-tolyl sulfone containing products are eligible for reregistration provided that: 1) all risk mitigation measures are implemented; 2) current data gaps and confirmatory data needs are addressed; and 3) label amendments are made as described in Section V. Appendix A summarizes the uses of diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone, the Agency has determined that diiodomethyl p-tolyl sulfone 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, submit confirmatory data as well as make the label changes identified in this document, the Agency may take regulatory action to address the risk concerns from the use of diiodomethyl p-tolyl sulfone. If all changes outlined in this document are fully complied with, then no risks of concern exist for the registered uses of diiodomethyl p-tolyl sulfone and 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 diiodomethyl p-tolyl sulfone. The EPA released its preliminary risk assessment for diiodomethyl p-tolyl sulfone for public comment on January 16, 2008. The Agency received comments from the technical registrant, Dow Chemical Company, in response to the EPA's draft diiodomethyl p-tolyl sulfone risk assessment (RA) and supporting science documents. The comments included suggestions to refine the hazard assessment and endpoint selection, and comments and suggestions regarding the exposure modeling scenarios used to conduct the ORE assessment. The technical registrant also provided the Agency with use information that was utilized to refine the human health risk assessment.

Other comments included suggestions for additional personal protection equipments (PPE) to reduce possible exposure risk to occupational workers. The Agency's response to these comments has been incorporated, as necessary, into the revised diiodomethyl p-tolyl sulfone 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-2007-1151). A Response to Comments document will be made available on the public docket in the future. In addition, comments received by the registrant during the Phase I, Error Only Comment Period of the RED process are available on the docket. The Agency is providing a 60-day public comment period for this RED document.

C. Regulatory Rationale

The Agency has determined that diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

The indirect food contact chronic dietary risks from diiodomethyl p-tolyl sulfone residues are below the Agency's level of concern for the treated adhesives, repeat-use rubber sealants, caulking material, and can side-seam cements. Therefore, no mitigation measures are necessary at this time.

b. Drinking Water Risk Mitigation

Diiodomethyl p-tolyl sulfone is not expected to come into contact with or be exposed to drinking water and, therefore, the Agency did not conduct a drinking water exposure assessment. Diiodomethyl p-tolyl sulfone is not used for potable water treatment and effluents containing this chemical are not expected to contact fresh water environments. Therefore, no mitigation measures are necessary at this time.

c. Residential Risk Mitigation

i. Handler Risk Mitigation

Residential handler dermal and inhalation risks were assessed for the application of Diiodomethyl p-tolyl sulfone treated paints via brush, roller, and airless sprayer; and the application of wood preservatives via brush, roller, and airless sprayer to treat wood surfaces.

Short-term dermal risks of concern were identified for residential paint application via airless sprayer (MOE = 48). To mitigate these risks of concern the registrant has agreed to lower the maximum application rate by 50% to 0.025 lb active ingredient (ai) for all paint application methods, excluding the roll-coat method. By lowering the maximum paint application rate by 50% the residential handler MOE for painting via airless sprayer is raised to 96 and, therefore, is no longer of concern. 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 with the lower maximum application rate. All product labels must be amended to incorporate the 50% decrease in application rates for paint use to mitigate residential paint application risks of concern.

For the paint roll-coat application method the Agency believes that there will be negligible exposure to residential and occupational handlers, and therefore, there are no risks of concern for this use. The roll-coater system is a surface coating application method in which the active ingredient is applied to oriented strand board (OSB) during the manufacturing processes. This surface coating is factory applied under controlled conditions only. Also, this coating is not available to residential or occupational painters. The Agency recognizes that the assumptions used in this risk assessment are conservative and believe that actual exposures may be less than those generated by the models in this particular case. Also, the Agency recognizes that this use pattern is limited to factory application only and believes that residential and occupational handler exposure as a result of this application method is negligible. Therefore, the application rate may remain at its current labeled maximum application rate of 0.05 lb ai for paint roll-coat use only. Restrictive language must be added to all paint labels indicating that diiodomethyl p-tolyl sulfone can be used at its current labeled rate for roll-coat application methods only and that the 50% lower application rates must be used for all other paint application methods.

For inhalation exposure, the target MOE for identifying risks of concern is 100 for short- and intermediate-term exposure durations. The target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However, if the inhalation MOE is greater than 100 but less than 1,000, inhalation toxicity data are needed to confirm that the use of route-to-route extrapolation (use of oral toxicity data to set an inhalation endpoint), as was done for diiodomethyl p-tolyl sulfone, does not underestimate inhalation exposure risk. The MOE for residential paint application via airless sprayer (MOE of 230 @ 0.05 lb ai; MOE = 460 @ 0.025 lb ai) is below the high-end target inhalation MOE of 1,000 even at the lower application rate. Because the inhalation MOE is below 1,000 for the airless sprayer use scenario, a confirmatory inhalation toxicity study is needed to further refine the inhalation risk assessment for the

residential handler in-can paint preservative airless sprayer use to confirm that the use of route-to-route extrapolations does not underestimate inhalation exposure risk.

ii. Post-Application Risk Mitigation

For the residential post-application assessment, representative scenarios were assessed for contact with surface residues from wood treated with diiodomethyl p-tolyl sulfone (dermal and incidental oral exposure to children); and for finger-painting activities (incidental oral exposure to children).

Incidental oral risks of concern were identified for finger-painting activities (MOE = 65-100). To mitigate the incidental oral finger-painting risks of concern, the registrant has agreed to lower the concentration of the active ingredient in finger-paint to 500 ppm active ingredient. By lowering the concentration, the MOE range is raised to 80-125. Given the uncertainties that exist with the predicted finger-painting exposure scenario and conservative Agency assumptions, the Agency believes that the predicted high-end range MOE of 125 is the most reasonable estimate of actual exposure. The MOE of 125 is above the target dermal MOE of 100 and, therefore, the Agency believes that there are no risks of concern for finger-painting if the maximum concentration rate is lowered to 500 ppm. All product labels must be amended to incorporate the lower concentration rate of 500 ppm to mitigate risks of concern for finger-painting. Originally, the Agency did not conduct an aggregate assessment for incidental oral exposure to children because individual risks of concern were identified for finger-painting. Because the Agency was able to mitigate the incidental-oral risks of concern for finger-painting by lowering the concentration rate to 500 ppm, an aggregate assessment for short-term incidental oral exposure to treated wood and finger-paint was conducted, using the updated MOE of 125. The aggregated total MOE for incidental oral exposure to treated wood and finger-paint is 102, and therefore not of concern because it is below the target MOE of 100.

It should be noted that the registrant has indicated that they do not intend to support the use of treated polymers/plastics for the use as toy products. The Agency requires the following label language for treated polymer/plastics labels to ensure that these products are not used to manufacture toys, "Treated plastics can not be used to manufacture children's toys." If labels are not amended to include this language, a risk assessment will be required for the use of diiodomethyl p-tolyl sulfone in plastic/polymer toys.

The technical registrant for diiodomethyl p-tolyl sulfone has also indicated that diiodomethyl p-tolyl sulfone is intended to treat carpet-backing only, not carpet fiber. The use of diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone in carpets, to carpet-backing only, by adding limitation language to the labels. As a result of the cancellation of the use of diiodomethyl p-tolyl sulfone to treat carpet fibers, and label language limiting the use of diiodomethyl p-tolyl sulfone to treat carpet-backing only, the Agency has determined that a post-application residential risk assessment is not needed to assess risks from treated carpet-backing. The rationale 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 diiodomethyl p-tolyl sulfone 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. However, if the carpet fiber use is not cancelled and labels are not amended to restrict the use of diiodomethyl p-tolyl sulfone to carpet-backing only, the Agency will have to assess possible exposure resulting from the use of diiodomethyl p-tolyl sulfone in carpet fiber.

d. Occupational Risk Mitigation

i. Handler Risk Mitigation

For occupational handlers the use of gloves, or personal protective equipment (PPE), is required on all product labels. Without the use of PPE several dermal risks of concern are identified. However, with the use of gloves (PPE) the MOEs for most exposure scenarios are above the target dermal MOEs. All occupational end-use labels must be amended to include language stating that gloves (PPE) must be used by workers. However, it should be noted that the Agency can not require the use of gloves (PPE) on in-can paint preservative labels.

Risks of concern have been identified for the application of paint via airless sprayer (Inhalation MOE = 67 ST; Dermal MOE = 29 ST). Short-term dermal risks of concern have also been identified for the application of paint via brush/roller (MOE = 62 ST). To mitigate these risks of concern the registrant has agreed to lower the application rate of treated paint by 50% to 0.025 lb active ingredient (ai) for all paint application methods, excluding the roll-coat method. By lowering the application rate by 50% the MOEs for painting via airless sprayer and brush/roller are raised above the target MOE of 100 (Painting via airless sprayer inhalation MOE = 135; Painting via brush/roller dermal MOE = 124 ST). The dermal exposure MOE for painting via airless sprayer is raised to 59, when the lower application rate is applied. The Agency recognizes that the assumptions used in this risk assessment are conservative (e.g., dermal and inhalation MOEs based on an oral endpoint) and believes that actual exposures may be less than those generated by the models in this particular case. Although the MOE of 59 is below the target MOE of 100, the Agency believes the risk assessment can be refined. Based on the reduced rate and the likelihood that exposure is overestimated, the Agency considers the identified risks to be adequately mitigated and do not pose a risk of concern. A 21-day dermal toxicity study is needed to confirm this determination and to better refine the exposure assessment. All product labels must be amended to incorporate the 50% decrease in the maximum application rate for paint use to mitigate occupational paint application risks of concern.

For the paint roll-coat application method, which is a factory applied surface coating, the Agency believes that there will be negligible exposure to residential and occupational handlers at its current maximum application rate of 0.05 lb active ingredient, and therefore, there are no risks of concern for this use. Therefore, the application rate may remain at its current labeled maximum application rate for paint roll-coat use only. Restrictive language must be added to all paint labels indicating that diiodomethyl p-tolyl sulfone can be used at its current labeled rate for

roll-coat application methods only, and that the 50% lower application rates must be used for all other paint application methods.

The preservation of paint via open pour wettable powder (WP) has a dermal exposure MOE of 83 with the use of gloves. Although the MOE of 83 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 (e.g., dermal MOE based on an oral endpoint) and the MOE is very close to the target of 100, the Agency believes that there are no dermal risks of concern resulting from this use. Therefore, mitigation is not needed for preservation of paint via open pour wettable powder.

The preservation of rubbers/plastics for open pour wettable powder formulations has a dermal MOE of 53 with the use of gloves. To mitigate risks of concern, the technical registrant has requested to voluntarily cancel preservation of rubbers/plastics for wettable powder formulation. All wettable powder formulation product labels must be amended to indicate that the wettable powder formulations can be used only for leather tanning, paper production, mold inhibition in paper and paperboard, and preservation in paper plant storage. The use of diiodomethyl p-tolyl sulfone for preservation of rubbers/plastics must be deleted from all wettable powder formulation labels. The technical registrant has also requested to voluntarily cancel the use of diiodomethyl p-tolyl sulfone for preservation of textiles/non-woven's and wood preservation for wettable powder formulations only. It should be noted that the requested rubber/plastics, textiles/non-woven's and wood preservation voluntary use cancellations are for wettable powder formulations only. These uses will remain active for all other formulation methods that are currently registered.

Occupational dermal risks of concern were also identified for treatment operator pressurized wood preservation (MOE = 69 IT). To mitigate treatment operator risks of concern the registrant has agreed to lower the dose rate from 1.0% to 0.7% lb active ingredient for pressure treatment wood preservation. By lowering the application rates the MOE for treatment operators is raised to 86. Although the MOE of 86 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 (e.g., dermal MOE based on an oral endpoint) and the MOE is very close to the target of 100, with the lower application rates. All product labels must be amended to incorporate the lower application rate of 0.8% w/w active ingredient for sapstain wood preservation and 0.7% lb active ingredient for pressure treatment wood preservation to mitigate occupational treatment operator risks of concern.

The use of respirators (PPE) is required on all wettable powder (WP) formulation product labels. Several occupational use scenarios have inhalation risks of concern for the wettable powder formulation uses without the use of a respirator. However, with a respirator there are no risks of concern for these uses. All wettable powder end-use labels must be amended to include language stating that respirators (PPE) must be worn by workers. However, it should be noted that the Agency can not require the use of respirators (PPE) on in-can paint preservative labels. When oral toxicity data are used to select an inhalation endpoint, as was done for diiodomethyl p-tolyl sulfone, it is Agency policy to consider requiring inhalation toxicity data to confirm that the use of route-to-route extrapolation does not underestimate potential risk. A high-end target

inhalation MOE of 1,000 was selected for diiodomethyl p-tolyl sulfone because the inhalation endpoint was based on an oral NOAEL. Several of the occupational handler exposures scenarios yielded MOEs below the high-end target of 1,000. For paint application, the MOE remains below the high-end target of 1,000 even with a 50% lower application rate. The following use scenarios trigger the need for confirmatory inhalation toxicity data because they have MOEs below 1,000: Paint application via airless sprayer (MOE = 135 @ 0.025 lb active ingredient); Paint preservation open pour wettable powder (MOE = 163 with respirator); Preservation of leather tanning drums open pour wettable powder (MOE = 210 with respirator); Blender spray operator for wood preservation (MOE = 203). Because the inhalation MOEs are below 1,000 for these use scenarios, a confirmatory inhalation toxicity study is needed to further refine the inhalation risk assessment for these occupational handler uses.

The technical registrant for diiodomethyl p-tolyl sulfone has indicated that for leather treatment, diiodomethyl p-tolyl sulfone is intended for leather tanning drum use only. Use of diiodomethyl p-tolyl sulfone for all other leather treatment applications must be deleted from all diiodomethyl p-tolyl sulfone labels. Also, all product labels must be amended to limit the use of diiodomethyl p-tolyl sulfone for leather tanning drum use only.

ii. Post-Application Risk Mitigation

Post-application occupational dermal risks of concern were identified for clean-up activities at a lumber mill (wood preservation) (MOE = 79 IT). To mitigate these risks of concern the registrant has agreed to lower the dose rate from 1.0% to 0.8% w/w active ingredient for sapstain wood preservation. By lowering the application rates the MOE for clean-up activities at a lumber mill is raised to 100, and therefore does not pose as a risk of concern. All product labels must be amended to incorporate the lower application rate of 0.8% w/w active ingredient for sapstain wood preservation mitigate post- application occupational dermal risks of concern for clean-up activities at lumber a mill.

For all post-application worker functions, the inhalation MOEs are above the target MOE of 100 and, therefore, are not of concern. A confirmatory inhalation toxicity study is no longer triggered by the clean-up crew scenario at the new application rate of 0.8% w/w active ingredient because the MOE is very close to the high-end target MOE of 1,000 at the new application rate (MOE = 920).

2. Environmental Risk Management

The EPA performed an environmental risk assessment using estimated environmental concentrations (EECs) for diiodomethyl p-tolyl sulfone, which were developed using various models. Toxicity values were also used to develop risk quotients (RQs) for comparison of levels of concern (LOCs). The models used in the ecological assessment are a conservative representation of all diiodomethyl p-tolyl sulfone wood preservative use scenarios.

Acute levels of concern (LOC) were not exceeded for non-listed freshwater fish or non-listed freshwater aquatic invertebrates for any scenario. However, freshwater fish and freshwater aquatic invertebrate LOCs were exceeded for listed (e.g., endangered and threatened) species for

all three dilution-rate scenarios from antisapstain use.

Several ecological species risk assessments for diiodomethyl p-tolyl sulfone are incomplete and/or could not be conducted due to data gaps or outstanding data. Therefore, to mitigate possible aquatic risks of concern, all wood preservative product labels must be updated to include the appropriate antisapstain label statement; and restrictive label language must be added that prohibits the use of pre-treated wood in structures located in surface waters (e.g., pilings) and prohibits topical application of diiodomethyl p-tolyl sulfone (e.g., brush on) to existing structures located or to be placed in surface waters (e.g., docks). If these label statements are not incorporated onto the wood preservative product labels or if the current uses for diiodomethyl p-tolyl sulfone are expanded, the ecological data described in section IV of this document will be needed to remove uncertainties and to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps. The following label language is needed to mitigate possible aquatic risks of concern:

Do not apply this product to any structure, or use any wood treated with this product in or above water or within 100 feet of any surface water or wetland area.

For the antisapstain use of diiodomethyl p-tolyl sulfone, the Agency used a Tier I screening model to estimate exposures that could result from this use. It should be noted that this model has inherent assumptions and uncertainties that may result in over or under estimation of exposure levels. Therefore, the registrant is responsible for amending all diiodomethyl p-tolyl sulfone 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, stream, 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."

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

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage

treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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 diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone. 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 antisapstain wood preservation uses, fall into this category.

The screening level assessment conducted for the antisapstain wood treatment uses of diiodomethyl p-tolyl sulfone indicates that there is a potential for use of this chemical to overlap with listed species and that a more refined assessment is warranted to include indirect, direct, and habitat effects. The refined assessment should involve clear delineation of the action area associated with proposed use of diiodomethyl p-tolyl sulfone and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this assessment. Due to these circumstances, the Agency defers from making an endangered species effect determination at this time. The label statement required for wood preservative products is expected to provide some mitigation until a full endangered species assessment is conducted. The revised labeling that is required in order for products to be considered eligible for reregistration is expected to provide some level of mitigation until such time as a full endangered species assessment is possible.

b. General Risk Mitigation

Diiodomethyl p-tolyl sulfone end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone 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 26). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For diiodomethyl p-tolyl sulfone 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 diiodomethyl p-tolyl sulfone, 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 26 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 Adam Heyward at (703) 308-6422 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:

Document Processing Desk
Adam Heyward
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
Adam Heyward
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 diiodomethyl p-tolyl sulfone 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

An inhalation toxicity study (OPPTS GL 870.3465) is needed as confirmatory data to refine the residential and occupational handler inhalation risk assessments for the following exposure scenarios: Residential handler paint application via airless sprayer (MOE = 460 @ 0.025 lb active ingredient); Occupational handler paint application via airless sprayer (MOE = 135 @ 0.025 lb active ingredient); Paint preservation open pour wettable powder (MOE = 163 with respirator); Preservation of leather tanning drums open pour wettable powder (MOE = 210 with respirator); Blender spray operator for wood preservation (MOE = 203). When oral toxicity data are used to select an inhalation endpoint, as was done for diiodomethyl p-tolyl sulfone, it is Agency policy to consider requiring inhalation toxicity data to confirm that the use of route-to-route extrapolation does not underestimate potential risk. A high-end target inhalation MOE of 1,000 was selected for diiodomethyl p-tolyl sulfone because the inhalation endpoint was based on an oral NOAEL. For inhalation MOEs below the target of 1,000, it is Agency policy to request confirmatory inhalation toxicity data to refine potential risks.

A 21/28-day dermal toxicity study (OPPTS GL 870.3200) is needed to confirm that there are no occupational risks of concern for handlers painting via airless sprayer (MOE = 59 @ 0.025 lb active ingredient). As previously noted the Agency recognizes that the assumptions used in this risk assessment are conservative (e.g., the dermal MOE is based on an oral endpoint) and believes that actual exposures may be less than those generated by the models in this particular case. Although the MOE of 59 is below the target MOE of 100, the Agency believes that this use does not pose as a risk of concern. However, a 21-day dermal toxicity study is needed to confirm this determination and to better refine the exposure assessment.

Surrogate data 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 (OPPTS GL 875.1200 & 875.1100, respectively), and inhalation exposure-indoor & outdoor data (OPPTS GL 875.1400 & 875.1300, respectively). Product use information (OPPTS GL 875.1700/ 875.2700) and description of human activity data (OPPTS GL 875.2800) are also needed to further define the exposure scenarios being supported and to further refine the assessments.

Residential Post-application Handler Confirmatory Data

A dislodgeable residue (surface wipe sampling) (GL 875.2300) study is needed as confirmatory data. Currently there are no data that can be used to estimate exposure to adults from inhalation from wood dust during construction of wood decks or to children exposed to treated wood. In the absence of data, the Agency conducted a screening-level assessment using a conservative surface residue value of 1 mg/cm^2 . Therefore, a wipe study is needed to confirm the screening level assessment.

Ecological Confirmatory Data

Several ecological species risk assessments for diiodomethyl p-tolyl sulfone are incomplete and/or could not be conducted due to data gaps or outstanding data. The registrant has agreed to amend all wood preservative product labels to include the appropriate antisapstain label statement; and restrictive label language that prohibits the use of pre-treated wood in structures located in surface waters (e.g., pilings) and prohibits topical application of diiodomethyl p-tolyl sulfone (e.g., brush on) to existing structures located or to be placed in surface waters (e.g., docks). These labels statements mitigate possible aquatic risks of concern. However, if these label statements are not incorporated onto the wood preservative product labels or if the current uses for diiodomethyl p-tolyl sulfone are expanded, the ecological data described in section IV of this document will be needed to remove uncertainties and to conduct and complete an ecological assessment for those species that could not be assessed as a result of data gaps.

Table 25 provides an outline of the requested confirmatory data for diiodomethyl p-tolyl sulfone.

Table #25. Confirmatory and Conditional Data for Diiodomethyl p-tolyl sulfone

Guideline Study Name	New OPPTS Guideline Number
<u>Human Health Confirmatory Data</u>	
21/28-Day Dermal Toxicity	870.3200
90-Day Inhalation Toxicity Data	870.3465
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
Surface Residue Dissipation Study ⁶	875.2300
Description of Human Activity Data	875.2800
<u>Environmental Fate & Ecological Exposure Confirmatory Data</u>	

⁶ To fulfill the dislodgeable residue surface wipe sampling study confirmatory data need, Guideline 875.2300 is needed. However, for the purpose of this assessment this study should not be conducted indoors.

Residues in honey/beeswax and toxicity of treated wood residues to bees <i>(This test can be waived provided that labels are amended as outlined for wood preservative use)</i>	Combination of Guideline 860.1500 and 850.3030
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2. Labeling for 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 Technical and 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 26 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 diiodomethyl p-tolyl sulfone RED. The following table describes how language on the labels should be amended.

Table #26 Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
All End Use Products		
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Occupational Use		
PPE Requirements for All End-Use product Intended for Occupational Use	"Occupational handlers must wear chemical resistant gloves while handling diiodomethyl p-tolyl sulfone."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements for Wettable Powder Formulations	"When handling wettable powder formulations of diiodomethyl p-tolyl sulfone, mixer loaders must wear NIOSH approved filtering face piece respirators."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Directions For Use		
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, stream, 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
End-use Products Intended for Wood Preservation/ Wood Treatment.	“Do not apply this product to any structure, or use any wood treated with this product in or above water or within 100 feet of any surface water or wetland area.”	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”	Directions for Use
End Use Products Intended for Carpet-backing Treatment	“Use only to treat carpet-backing. Not for use in carpet fibers.”	Directions for Use
End Use Products Intended for Leather Tanning Drum Treatment	“For use in leather tanning drum use only.”	Directions for Use
For all Wettable Powder Formulations	“Wettable powder formulations can be used only for leather tanning, paper production, mold inhibition in paper and paperboard, and preservation in paper plant storage.”	Directions for Use
End-Use Products Intended for Paint-Preservation	All paint preservation product labels must be amended to indicate that a maximum application rate of 0.05 lb active ingredient is for roll-coat paint application only. The maximum application rate for all other paint application exposure scenarios/methods, including airless sprayer and brush/roller application, is 0.025 lb active ingredient.	Directions for Use
End-Use Products Intended for Antisapstain Wood Preservation	All antisapstain wood preservation product labels must be amended to state that the maximum application rate is 0.8% w/w active ingredient for sapstain wood preservation.	Directions for Use

End-Use Products Intended for Pressure Treatment Wood Preservation.	All pressure treatment wood preservation product labels must be amended to state that the maximum application rate is 0.7 lb active ingredient for pressure treatment wood preservation.	Directions for Use
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VI. APPENDICES

Appendix A. Table of Use Patterns for Diiodomethyl p-tolyl sulfone

	Product Name	EPA Registration Number	Application Method	Intended Uses	Lower App Limit	Upper App Limit	Units	Use Limitations
Paint	AMICAL 48	464-670	Add to pigment grind	Dry Film Mildewicide Algicide	1	5	lb/100 gal	
	AMICAL WP	464-672	Add to pigment grind	Dry Film Mildewicide Algicide	3	10.2	lb/100 gal	
	AMICAL Flowable	464-673	Add	Dry Film Mildewicide Algicide	2.5	12.5	lb/100 gal	
					0.37		fl oz / gal	
	Ultra-Fresh 15	10466-37	Add	Dry Film Mildewicide Algicide	10.7	26.7	lb/100 gal	
	Intace Fungicide B-6773	74075-1	Add	Dry Film Mildewicide Algicide	2	20.0	lb/1000 gal	Non-Food Contact
Air Duct Coatings	AMICAL 48	464-670	Add to pigment grind	Dry Film Mildewicide Algicide	1	5	lb/100 gal	
	AMICAL WP	464-672	Add to pigment grind	Dry Film Mildewicide Algicide	3	10.2	lb/100 gal	
	AMICAL Flowable	464-673	Add	Dry Film Mildewicide Algicide	2.5	12.5	lb/100 gal	
Fire-Retardant Coatings	AMICAL 48	464-670	Add with mixing	Dry Film Mildewicide	0.0015%	0.3%	w/w	
	AMICAL WP	464-672	Add with mixing	Dry Film Mildewicide	0.02%	0.61%	w/w	
	AMICAL Flowable	464-673	Add	Dry Film Mildewicide	0.00375%	0.75%	w/w	

Pigment Dispersions, Inks, Emulsions, Extender Slurries	AMICAL 48	464-670	Add with mixing	Fungal Preservative	0.02%	0.15%	w/w	
	AMICAL WP	464-672	Add with mixing	Fungal Preservative	0.10%	0.31%	w/w	
	AMICAL Flowable	464-673	Add with mixing	Fungal Preservative	0.05%	0.38%	w/w	
	Ultra-Fresh 15	10466-37	Add with mixing	Fungal Preservative	0.13%	1%	w/w	
Adhesives, Caulks, and Sealants	AMICAL 48	464-670	Add with mixing	Dry Film Mildew Control / Fungal Preservative	0.01%	0.30%	w/w	
	AMICAL WP	464-672	Add with mixing	Dry Film Mildew Control / Fungal Preservative	0.04%	0.61%	w/w	
	AMICAL Flowable	464-673	Add with mixing	Dry Film Mildew Control / Fungal Preservative	0.025%	0.72%	w/w	
					0.044	0.176	fl oz/gal	
	Ultra-Fresh 15	10466-37	Add with mixing	Dry Film Mildew Control / Fungal Preservative	0.067%	1.90%	w/w	Non-food contact
Wood Preservation	Intace Fungicide B-6773	74075-1	Add with mixing	Dry Film Mildew Control / Fungal Preservative	2	20	gal/1000 gal	Non-food contact
	AMICAL 48	464-670	Formulate	Formulations for mildew, sapstain, and rot control	0.30%	1.0%	w/w	Use to formulate only
	AMICAL WP	464-672	Formulate	Formulations for mildew, sapstain, and rot control	0.61%	2.0%	w/w	Use to formulate only
	AMICAL Flowable	464-673	Add to water-based treatment	Mildew, sapstain, rot control	0.30%	1.00%	w/w ACTIVE	Above Ground Use Only

			Spray treat	Mildew, sapstain, rot control	0.50%		w/w ACTIVE	Above Ground Use Only
			Dip	Mildew, sapstain, rot control	1 minute			Above Ground Use Only
			Pressure Treat	Mildew, sapstain, rot control	0.05	1.00	lb pcf	Above Ground Use Only
	Ultra-Fresh 15	10466-37	Add to water-based treatment	Mildew, sapstain, rot control	0.10%	1.00%	w/w ACTIVE	Above Ground Use Only
			Spray treat	Mildew, sapstain, rot control	0.50%		w/w ACTIVE	Above Ground Use Only
			Pressure Treat	Mildew, sapstain, rot control	0.13	2.70	lb pcf	Above Ground Use Only
	Wolman Clear Wood Preservative	60061-9	Brush, Dip Roller, or Spray	Mold, mildew, bacteria, decay, algae, and termite protection	150	300	sq ft/gal	Above Ground Use Only
	Bazooka	60061-112	High-pressure spray	Mildew, sapstain, rot control	0.002	0.5	gal/gal water	
			Dip Application	Mildew, sapstain, rot control	0.001	0.05	gal/gal water	
Metalworking Fluids	AMICAL 48	464-670	Add to diluted fluid	Fungal control	100	3000	ppm	
	AMICAL WP	464-672	Add to diluted fluid	Fungal control	204	6122	ppm	
	AMICAL Flowable	464-673	Add to diluted fluid	Fungal control	240	7200	ppm	
	Ultra-Fresh 15	10466-37	Add to diluted fluid	Fungal control	600	1900	ppm	
Rubber and Plastics	AMICAL 48	464-670	Add	Dry-film fungal protection	0.1%	0.8%	w/w	
	AMICAL WP	464-672	Add	Dry-film fungal protection	0.20%	1.6%	w/w	

	Ultra-Fresh 15	10466-37	Add	Dry-film fungal protection	0.50%	1.50%	w/w	
Textiles and Non-Wovens (non-clothing)	AMICAL 48	464-670	Add	Dry-film fungal protection	0.5	5	lb/1000 lb fabric	Non-clothing
	AMICAL WP	464-672	Add	Dry-film fungal protection	1	10	lb/1000 lb dry fabric	Non-clothing
	AMICAL Flowable	464-673	Add	Dry-film fungal protection	1.25	12.5	lb/1000 lb dry fabric	Non-clothing
	Ultra-Fresh 15	10466-37	Add	Dry-film fungal protection	3.3	33.4	lb/1000 lb dry fabric	Non-clothing
Leather Tanning	AMICAL 48	464-670	Detailed on Label	In-process mold and mildew protection	0.01%	0.30%	w/w	
	AMICAL WP	464-672	Detailed on Label	In-process mold and mildew protection	0.02%	0.61%	w/w	
	AMICAL Flowable	464-673	Detailed on Label	In-process mold and mildew protection	0.02%	0.66%	w/w	
	Ultra-Fresh 15	10466-37	Detailed on Label	In-process mold and mildew protection	0.053%	1.2%	w/w	
Paper Production	AMICAL 48	464-670	Add to system where mixing occurs	Protection of water system, pulp, additives, and slurries	0.0008	0.8	lb/ton paper	Not for food contact
					0.004	3.32	lb/1000 gal	
	AMICAL WP	464-672	Add to system where mixing occurs	Protection of water system, pulp, additives, and slurries	0.0016	1.6	lb/ton paper	Not for food contact
					0.008	6.78	lb/1000 gal	

Mold Inhibition in Paper and Paperboard	AMICAL Flowable	464-673	Add to system where mixing occurs	Protection of water system, pulp, additives, and slurries	0.0019	1.92	lb/ton paper	Not for food contact
					0.0096	7.97	lb/1000 gal	
	Ultra-Fresh 15	10466-37	Add to system where mixing occurs	Protection of water system, pulp, additives, and slurries	0.0051	5.13	lb/ton paper	Not for food contact
					0.026	21.3	lb/1000 gal	
	AMICAL 48	464-670	Add to whitewater or stock	Dry-film fungal protection	0.02	3.4	lb/ton paper	
			Applicator rolls or shower		0.02	3.4	lb/ton paper	
			Size press or water box		80	8000	ppm	
	AMICAL WP	464-672	Add to whitewater or stock	Dry-film fungal protection	0.04	6.9	lb/ton paper	
			Applicator rolls or shower		0.04	6.9	lb/ton paper	
			Size press or water box		163	16300	ppm	
	AMICAL Flowable	464-673	Add to whitewater or stock	Dry-film fungal protection	0.54	8.21	lb/ton paper	
			Applicator rolls or shower		0.048	8.16	lb/ton paper	
			Size press or water box		200	20000	ppm	
	Ultra-Fresh 15	10466-37	Add to whitewater or stock	Dry-film fungal protection	0.13	21.8	lb/ton paper	
			Applicator rolls or shower		0.13	21.8	lb/ton paper	
			Size press or water box		540	54000	ppm	

	Intace Fungicide B- 6773	74075-1	Add	Dry-film fungal protection	350	2500	ppm	
Paper Plant Storage	AMICAL 48	464-670	Add to material to be preserved	Fungal Preservative	0.2	400	ppm	
	AMICAL WP	464-672	Add to material to be preserved	Fungal Preservative	0.4	816	ppm	
	AMICAL Flowable	464-673	Add to material to be preserved	Fungal Preservative	0.2	400	ppm active	
	Ultra-Fresh 15	10466-37	Add to material to be preserved	Fungal Preservative	0.2	400	ppm active	
Nitrocellulose	AMICAL 48	464-670	Add to material	Fungal Preservative	0.05%	0.30%	w/w	
Drain, Grease Trap and Septic System	AMICAL Flowable	464-673	Add	Fungal Control	125	1000	ppm	

APPENDIX B: Diiodomethyl p-tolyl sulfone (Case 4009)

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

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.
2. **Guideline Description** (Column 3). Identifies the guideline type.
3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.
 - (1) Agricultural premises and equipment
 - (2) Food handling/ storage establishments' premises and equipment
 - (3) Commercial, institutional and industrial premises and equipment
 - (4) Residential and public access premises
 - (5) Medical premises and equipment
 - (6) Human water systems
 - (7) Materials preservatives
 - (8) Industrial processes and water systems
 - (9) Antifouling coatings
 - (10) Wood preservatives
 - (11) Swimming pools
Aquatic areas
3. **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
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition		4590901
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process		42054401
	61-3	Discussion of Formation of Impurities		4590901
830.1750	62-2	Certification of Limits		4590901
830.1800	62-3	Analytical Method		4590901
	63-0	Reports of Multiple phys/chem Characteristics		45757402
830.6302	63-2	Color		42054401
830.6303	63-3	Physical State		42054401
830.6304	63-4	Odor		42054401
830.7050	none	UV/Visible absorption		472340-03
830.7200	63-5	Melting Point		42054401
830.7300	63-7	Density		42054401
830.7840 830.7860	63-8	Solubility		42054401
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)		421772-02
830.7000	63-12	pH		42054401
830.6313	63-13	Stability		In Review
830.6315	63-15	Flammability		Required

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
<u>ECOLOGICAL EFFECTS</u>				
850.1010	72-2	Acute Aquatic Invertebrate Toxicity		149729, 149729
850.1075	72-1	Fish Acute Toxicity – Freshwater (Rainbow Trout)		149730
850.2100	71-1	Avian Acute Oral Toxicity Test (Quail/Duck)		123642, 123643
<u>TOXICOLOGY</u>				
870.1100	81-1	Acute Oral - Rat		42586801, 43008702, 41765401
870.1200	81-2	Acute Dermal - Rabbit		00123023, 00141066
870.1300	81-3	Acute Inhalation - Rat		43660901, 00087842
870.2400	81-4	Primary Eye Irritation - Rabbit		41765402, 43008703
870.2500	81-5	Primary Dermal Irritation - Rabbit		41765403, 43008704, 00141066
870.2600	81-6	Dermal Sensitization		00230726, 00141067, 00054963
870.3150	82-1	Subchronic Oral Toxicity: 90-Day Study-Dog		43246402, 42054403, 43246402
870.3100	82-1	Subchronic Oral Toxicity: 90-Day Study- Rat		43246401, 42054402
870.3100	82-1	90-Day Feeding-Rodent		42054402, 43246401
870.3150	82-1	90-day feeding-nonrodent		43246402
870.3200	82-2	21/28-Day Dermal Toxicity - Rat		Data Gap
870.3465	82-4	90-Day Inhalation Toxicity - Rat		Data Gap
870-3700	83-3	Teratogenicity -- 2 Species		42054404, 42054405, 42243801, 43246403, 43246404, 41161801
870.3700	83-3	Prenatal developmental toxicity study		47242202
870.3700	83-3	Developmental Study – Rat		42054404, 42054405
870.3700	83-3	Developmental Study – Rabbit		42243801, 47242202

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.3800	83-4	Reproduction and fertility effects		46913302, 46913301
				00054961, 00054962
870.5100	84-2	Bacteria reverse Mutation Study		
870.5265	84-2	Bacterial Reverse Mutation Assay		00054962
870.5300	84-2	Detection of gene mutations in somatic cells		00160070, 00054961
	84-4	Other genotoxic effects		160072
870.5375	84-2	Mammalian Mutagenicity Tests		43120601
870.5395				00160072, 00160070
870.5550	84-2	Intreration with Gonadal DNA		00054962, 00160071
870.7485		Metabolism and pharmacokinetics		47076601, 47078801
	84-2b	Struct. chrom. aberration		43120601
	152-19	Mammalian Mutagenicity Tests		43120601
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis of parent and degradates as a function of pH at 24 C		43008701
835.4100	162-1	Aerobic soil metabolism		41765405
835.4200	162-2	Anaerobic soil metabolism		41765406
835.4400	162-3	Anaerobic aquatic metab.		42177201
835.1230 835.1240	163-1	Leach/adsorp/desorption		41765407, 43997001

<u>ECOLOGICAL EFFECTS</u>				
850.2100	71-1	Avian Single Dose Oral Toxicity		123643, 94039001
850.2200	71-2	Avian Dietary Toxicity		123642, 124488, 94039002, 94039003
850.1075	72-1	Acute Toxicity to Freshwater Fish		94039004, 94039005, 149730, 149731
850.1010	72-2	Acute Toxicity to Freshwater Invertebrates		94039006, 149729, 123644
850.1400	72-4	Fish Early Life Stage/Aquatic Invertebrate Life Cycle Study		55326
<u>DATA REQUIREMENT</u>				<u>CITATION(S)</u>
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
<u>ORE</u>				
875.1100		Dermal exposure- Outdoor		Data Gap
875.1200		Dermal Exposure- Indoor		Data Gap
875.1300		Inhalation Exposure- Outdoor		Data Gap
875.1400		Inhalation Exposure- Indoor		Data Gap
875.1700 & 875.2700		Product Use Information		Data Gap
875.2300		Surface Residue Dissipation Study		Data Gap

875.2400	133-3	Dermal passive dosimetry expo		455243-04
875.2500	133-4	Inhal. passive dosimetry expo		455243-04
875.2800		Description of Human Activity		Data Gap

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 June 28, 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 diiodomethyl p-tolyl sulfone, 03/31/2008

Revised Risk Assessment and Supporting Science Documents:

- Diiodomethyl p-tolyl sulfone. P.C. Code: 101002. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. Case 4009, 4/29/2008
- Diiodomethyl p-tolyl sulfone: Hazard Assessment, 3/14/2008
- Amended Product Chemistry of Benzene, 1-((diiodomethyl)sulfonyl)-4-methyl or Diiodomethyl p-tolyl sulfone for the Reregistration Eligibility Decision (RED), 2/28/2008
- Revised Occupational and Residential Exposure Chapter for Diiodomethyl-p-tolylsulfone, 3/27/2008
- Revised Environmental Hazards and Ecological Risk Assessment for the Diiodomethyl p-tolyl sulfone RED, 3/12/2008
- Environmental Fate Assessment of Di-iodomethyl p-tolyl sulfone for RED, 3/26/2008

Preliminary Risk Assessment and Supporting Science Documents:

- Diiodomethyl p-tolyl sulfone. P.C. Code: 101002 Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. Case 4009, 1/10/2008
- Diiodomethyl p-tolyl sulfone: Hazard Assessment, 1/9/2008
- Diiodomethyl p-tolyl sulfone- Incident Report, 1/9/2008
- Amended Product Chemistry for Benzene, 1-(diiodomethyl)sulfonyl)-4-methyl or Diiodomethyl p-tolyl sulfone for the Reregistration Eligibility Decision (RED),

- 1/9/2008
- Revised Dietary and Drinking Water Exposure Chapter for Diiodomethyl p-tolyl sulfone for the Reregistration Eligibility Decision (RED) Document (Case 4009), 1/2/2008
- Occupational and Residential Exposure Chapter for Diiodomethyl-p-tolylsulfone, 1/9/2008
- Revised Environmental Hazards and Ecological Risk Assessment for the Diiodomethyl p-tolyl sulfone RED, 1/8/2008
- Environmental Fate Assessment of Diiodomethyl p-tolyl sulfone for RED, 1/9/2008

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

1. MRID Studies

<u>MRID#</u>	<u>Citation</u>
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4590901	Gonsior, S et al., 2002: Estimating Soil Adsorption Coefficient Loc for Series of Biocides by HPLC Using OECD Method 121: Submitted by Dow Chemical Company.
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47242202	Carney, E., K. Brooks, R. Rasoulpour, et al. (2007) AMICAL™ 48, antifungal agent: oral gavage developmental toxicity study in New Zealand white rabbits. The Dow Chemical Company. Laboratory Project Study ID 061146, August 29, 2007. MRID 47242202. Unpublished.

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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In (DCI) at a later date. See Chapter V of the diiodomethyl p-tolyl sulfone 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 (DCI) at a later date.

Appendix G. Batching of Diiodomethyl p-tolyl sulfone Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching for diiodomethyl p-tolyl sulfone at a later date.

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

A list of registrants sent the data call-in (DCI) 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.