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Prevention, Pesticides and Toxic Substances

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Reregistration Eligibility Decision for Creosote (Case 0139)

Reregistration Eligibility Decision (RED) Document

for

Creosote

Case 0139

Approved by: [signature]
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Date: September 25, 2008

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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	Protections 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 creosote and is issuing its risk management decision. The risk assessments, which are summarized below, are based on the review of the required registrant submitted data supporting the use patterns of currently registered products, citations from open literature, and additional information received through the docket. The risk assessments have been revised, as needed, according to information received since they were last made available to the public in April through June 2008. After considering the risks assessments, available information about alternatives to creosote, public comments, and risk mitigation options, the Agency developed its reregistration eligibility and risk management decision for wood preservative uses of creosote. As a result of this review, EPA has determined that creosote containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. The reregistration eligibility decision and associated risk mitigation measures are 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 Creosote. The creosote case consists of one PC code each: 022003, 025003 and 25004. The first product containing creosote was registered in 1948.

Creosote is a fungicide, insecticide, and sporicide used as a wood preservative for above and below ground wood protection treatments as well as for treating wood in marine environments. All 14 Creosote products currently registered are Restricted Use Pesticides; 13 are End-Use Products and 1 is a Manufacturing-Use Product for formulating industrial end-use wood preservative products. Creosote wood preservatives are used primarily to pressure treat railroad ties/crossties (represents close to 70% of all Creosote use) and utility poles/crossarms (represents 15 - 20% of all Creosote use). Assorted Creosote-treated lumber products (e.g., timbers, poles, posts and groundline-support structures) represent the remaining uses for this wood preservative. The industry refers to different blends of creosote, based on the wood treatment standards set by the American Wood-Preservers' Association (AWPA), as P1/P13 and P2. Typically, railroad ties/crossties are treated with a P2 blend, which is more viscous than the P1/P13 blend used for treating utility poles.

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 creosote as an active ingredient. Therefore, a 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 creosote. 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 creosote referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at www.regulations.gov (Docket ID #EPA-HQ-OPP-2003-0248).

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 creosote and its regulatory history. Section III, Summary of Creosote's 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

Creosote has been registered as a heavy duty wood preservative since 1948. There currently are five primary registrants collectively holding a total of thirteen industrial wood preservative product registrations (1 manufacturing use product and 13 end-use products) for above and below ground wood protection as well as treating wood in marine environments. As a result of the voluntary cancellation of non-pressure treatment end-use registrations and removal of non-pressure treatment uses on other creosote products initiated by the creosote registrants in 2003, creosote is a restricted use pesticide that can only be applied by pressure-treatment. Creosote wood preservatives are used primarily in the pressure treatment of railroad ties/crossties (about 70% of all Creosote use) and utility poles/cross-arms (about 15 - 20% of all Creosote use). Assorted Creosote-treated lumber products (e.g., timbers, poles, posts and ground-line support structures) account for the remaining uses for this wood preservative.

Since creosote is derived from the distillation of coal tar, consists of hundreds of compounds, and has a variable composition, the American Wood Protection Association (AWPA) formerly known as the American Wood-Preservers" Association established standards to differentiate between the different blends of creosote. For instance, P1/P13 and P2 are the predominant blends used by the wood treating industry. Typically, railroad ties/crossties are treated with a P2 blend which has a higher distillation residue making it more viscous than the P1/P13 blend typically used for treating utility poles.

In October 1978, an administrative review process was initiated to consider whether creosote as well as the other two heavy duty wood preservatives, Pentachlorophenol and Chromated Arsenical uses should be canceled or modified. The Federal Register (Vol.49, No.139) of July 13, 1984 concluded that process and announced that certain changes in the terms and conditions of registration were required if registrants and applicants wished to avoid cancellation.

The Agency considered the potential risks to public health posed by Creosote (and the other heavy duty wood preservatives) along with the benefits resulting from their use. As a result of this evaluation, the Agency determined that the use of creosote as a wood preservative chemical met the statutory standard for registration provided that certain risk mitigation measures were implemented. These modifications required that Creosote be classified as restricted use pesticide, workers were required to use certain protection/protective clothing and equipment and Creosote use was restricted to non-residential use sites. These mitigation measures are noted in the Federal Register January 13, 1986 (Vol.51, No. 7).

B. Chemical Identification

Creosote, as defined by the American Wood Preservers Association, is a distillate derived from coal tar, derived by the high temperature carbonization of bituminous coal. Creosote consists primarily of liquid, solid polycyclic aromatic hydrocarbons (PAHs), other heteronuclear aromatic substances, and some tar acids and bases. USEPA's document, "Guidance for Reregistration of Pesticide Products Containing Coal Tar Creosote"[1] recognizes that "hundreds of individual chemicals have been identified in coal tar creosote."

Table 1. Active Ingredient Summary for Chemical Case 0139

Chemical Name	Coal Tar	Creooste Oil	Coal Tar Creosote
PC Chemical Code	22003	25003	25004
CAS Number	8007-45-2	61789-28-4	8001-58-9
Common Name	Creosote Oil		

There are two major types of creosote, P1/P13 fraction which is used in the treatment of poles and pilings and P2 fraction which is used in the treatment of railroad ties. These two fractions of creosote are derived by carbonizing coal through high temperature distillation and collecting the coal tar fractions that are comprised of light oil, middle oil, and heavy (oil) anthracene. The middle oil fraction is further distilled creating additional fractions. P1/P13 and P2 fractions are collected when the middle oil temperature is between 210^{o}C and 355^{o}C.

[1] USEPA Document 540-RS-88-066. Guidance for the Registration of Pesticide Products containing Coal Tar/Creosote.

P1/P13 Fraction[2]

Color:	2.5Y/2 to 2.5Y4/2 (Based on Munsell color scheme)
Odor:	Sharp, aromatic, wood-like
Solubility:	313 ug/ml[3]
Vapor Pressure:	11.1 mm Hg at 24.4oC
Log P:	3.247
Viscosity:	14.60 mm/s
Stability:	Short-term (accelerated) stability was performed on four constituents of the mixture: naphthalene, penanthrene pyrene and chrysene for a period of 30 day at 60oC. At the end of thirty days, the remaining naphthalene, phenanthrene, pyrene, and chrysene were 96.5%, 87.2%, 86.9%, and 92.4%, respectively.

P2 Fraction

Color:	10YR2 to 2.5Y5/5 (Based on Munsell color scheme)
Odor:	Strong aromatic Petroleum-like
Solubility:	306 ug/ml
Vapor Pressure:	8.6 mm Hg at 24.4 to 24.5oC
Log P:	3.311
Viscosity:	15.5 mm/s at 25oC

Currently there are 13 end-use products (EUP) registered for pressure treatment of wood intended for above ground and ground contact, as well as in fresh water and marine environments, and 1 manufacturing use products (MUP) containing directions for further formulation into wood preservatives. Wood treated with these preservatives is specified for commercial and industrial uses at outdoor sites. Creosote formulations intended for use as a wood treatment are Restricted Use Pesticides.

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[2] The P1/P13 samples, provided by the Industry to Research Triangle Institute, were distilled within 95% confidences limit. The remaining residues were less than 1.1% as required by the AWPA Standard A1-91
Moisture content for industry sample (single determination) is 0.4%
Specific gravity of fraction, for industry sample (single determination) is 1.0934 (corrected to 38oC)

[3] Insoluble mass in Xylenes: Duplicate determinations showed that this fraction contained between 0.21 to 0.23% insoluble materials.

Table 2 presents a summary of the active Manufacturing Use Products (MUP) and End-Use Products (EUP) considered for reregistration.

Table 2. Active Registrations in Case 0139

Company	EPA Reg. No.	Product Name	MUP	EUP
Coopers Creek Chemical	363-14	The C-4 Brand Black Creosote Coal Tar Solution		x
	363-15	The C-4 Brand Coopersote Creooste Oil		x
	363-48	P-2 Creosote Petroleum Solution		x
Koppers, Inc	61468-1	Coal Tar Creosote (Pressure Applications)		x
	61468-3	Creosote Solution (Pressure Applications)		x
	61468-6	Creosote Manufacturing Use	x	
	61468-9	Creosote/Petroleum Solution		x
Rutgers VFT	61470-1	KMG-B Coal Tar Creosote		x
KMG-Bernuth Inc	61483-8	Creosote Coal Tar Solution		x
	61483-9	Creosote Oil		x
	61483-11	P1/P2 Creosote Oil		x
	61483-12	P2 Creosote Coal Tar Solution		x
Tangent Rail Products, Inc	73408-1	Creosote		x
	73408-2	Creosote Solution		x

No tolerance currently exists for the wood preservative uses of creosote.

C. Use Profile

The following information is a description of the currently registered uses of creosote, and an overview of use sites and application methods. A detailed table of uses for creosote that are eligible for registration can be found in Appendix A.

Type of Pesticide: Fungicide, Insecticide, Miticide, and Sporicide

Use Sites: Terrestrial and aquatic nonfood wood/wood structure protection treatments via pressure methods to utility poles/crossarms, railroad ties, fences, fence posts, foundation timbers, timbers, lumber, and pilings. Treated wood intended for exterior/outdoor uses only.

Target Pests:	Wood Destroying Insects, Wood Boring Insects, Roundheaded Wood Borers, Marine Borers, Wood Infesting Insects, Termites, Beetles, Powderpost Beetles, Bees, Carpenter Bees, Carpenter Ants, Dry Rot Fungi, Wood Rot/Decay Fungi, Wood Rot/Decay Organisms, Slime
Formulation Types:	Soluble concentrate and ready-to-use
Methods and Rates of Application:	Pressure Treatment using a pressure treating vessel at a rate of 12 lbs. per cu. ft..

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for the wood preservatives containing creosote. These estimates are derived from a variety of published and proprietary sources available to the Agency.

Based on EPA proprietary data and public literature, the Agency estimates that approximately 87 million gallons of creosote were used in 2004. Currently, creosote represents 99% of the US market for wood treated crossties, bridge and switch ties. In addition to railroad ties, creosote is an important preserver for utility poles. Creosote accounts for approximately 16% of the treated utility pole market (the remaining percentage being treated with pentachlorophenol or chromated arsenicals).

According to AWPA estimates of 1997, there are fifty-seven wood treatment plants in U.S. that use creosote to treat approximately 93 million cubic feet of wood annually.

E. Disposal Information

In a broad sense, two types of waste are generated through the use of creosote wood preservatives: wood treated with creosote and industrial waste generated through the application of creosote. The disposal requirements differ for each type of waste.

1. Treated Wood

Discarded creosote-treated lumber is usually land disposed in either construction and demolition landfills, municipal solid waste landfills, or industrial non-hazardous waste landfills. Under the existing federal hazardous waste regulations, wastes containing certain constituents, such as arsenic, are defined as hazardous waste if a representative sample of that waste leaches arsenic above a certain threshold concentration, using a specified testing procedure. While it has been shown that some creosote-treated wood meets this definition, discarded creosote treated wood is generally not subject to regulation as a hazardous waste. This is because of an existing exemption at 40 CFR 261.4(b)(9), originally promulgated in the November 25, 1980 *Federal Register* (45 FR 78530).

Currently, many state and local governments have specific regulations, guidelines, or recommendations for the management and disposal of discarded creosote-treated wood, either explicitly, or sometimes under the larger category of "treated wood." In addition, some states have developed, or are developing, legislation and regulations to prohibit or restrict activities such as burning creosote-treated wood, producing wood mulch using creosote-treated wood, and disposing of creosote-treated wood in 'unlined' construction and demolition landfills. Therefore, EPA recommends that persons contact their state and local authorities regarding specific policies or regulations concerning the disposal of creosote-treated wood.

EPA estimates that there will remain a supply of creosote and creosote-treated wood that will ultimately require disposal, considering the amount of this railroad ties and marine pilings currently in use, and their typical service life (which can be many years). EPA continues to evaluate the potential impacts of land disposal of discarded creosote-treated wood. In the meantime, EPA has recommended that the land disposal of this material take place in a manner that minimizes any possibility of releases of hazardous constituents to groundwater resources. Specifically, in a memorandum dated April 12, 2004, EPA recommended that if discarded creosote-treated wood is to be disposed in a landfill, the landfill should be designed to satisfy the standards for protecting groundwater in 40 CFR 258.40, which contain design and performance criteria applicable to municipal solid waste landfills. EPA's goal is to promote the sensible management of this material, by encouraging the use of landfills that meet these standards (whether through specific design criteria or through demonstrating compliance with performance standards) to ensure the utility of groundwater resources.

2. Waste Generated at Wood Treatment Facilities

There are also hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) that apply specifically to wastes generated at facilities where wood preservatives are used to treat wood. On December 6, 1990 EPA promulgated several hazardous waste listings applicable to wastes generated by wood treaters using certain wood preservative chemicals. (55 *FR* 50450; December 6, 1990 *Federal Register*). One of these hazardous waste listings (Hazardous Waste Number F034) can be found in the hazardous waste regulations at 40 CFR 261.31, and reads as follows:

> F034 - Wastewaters (except those that have not come into contact with process contaminants), process residuals, preservative drippage, and spent formulations from wood preserving processes generated at plants that use creosote formulations. This listing does not include K001 bottom sediment sludge from the treatment of wastewater from wood preserving processes that use creosote and/or pentachlorophenol.

III. Summary of Creosote Risk Assessments

The purpose of this section is to summarize EPA's human health and ecological risk estimates for wood preservative uses of creosote to help the reader better understand EPA's risk management decisions. 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 creosote. The full risk assessments and related supporting documents are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2003-0248.

EPA developed this RED for the wood preservative uses of creosote through a 6–Phase public participation process. The Agency uses public participation processes to involve the public in developing pesticide reregistration decisions. EPA released its preliminary and revised risk assessments for 60-day public comment in March 2004 and April 2008, respectively. Substantive comments were incorporated into the final risk assessments which were used to make this reregistration eligibility decision.

A. Background on Wood Preservative Assessment

For almost all pesticides subject to reregistration, EPA employed an active ingredient-focused approach rather than an application method-focused approach. That is, EPA typically evaluated and made reregistration eligibility decisions for each active ingredient and its associated use sites rather than each use site and its associated active ingredients ("RED for active ingredient X" rather than "RED for applications made by application method X"). However, due to the unique nature in which the chemicals are applied, EPA made the decision early in the reregistration process (circa 1988) to evaluate heavy duty wood preservative uses collectively using an application method-focused approach.

The term "heavy duty" wood preservative is used to differentiate wood preservatives applied using specialized high pressure treatment cylinders (also called "retorts") from those applied using non-specialized methods (e.g., brush, dip). Figure 1 presents a photograph of a treatment retort. There are three heavy duty wood preservative cases subject to reregistration: chromated arsenicals (Case 0132), pentachlorophenol (Case 2505), and creosote (Case 0139). Because these cases include only heavy duty wood preservatives, to improve readability the words "heavy duty" are often omitted in favor of the generic term "wood preservative" throughout the RED and supporting documents. The Agency notes that other heavy duty wood preservatives exist outside Case 0132, 2505, and 0139; however, uses of these preservatives were not subject to reregistration because the chemicals were not registered prior to November 1, 1984 and are therefore outside the scope of the three heavy duty wood preservative REDs. Heavy duty wood preservatives not included in Case 0132, 2505, and 0139 will be evaluated in the future under the registration review program.

Figure 1. Heavy Duty Wood Preservative High Pressure Treatment Cylinder (Retort)

Again, due to the unique nature in which heavy duty wood preservatives are applied, wood preservative risk assessment requires a different approach than those used for standard agricultural or antimicrobial pesticides. For example, unlike agricultural pesticide handlers who may be exposed to pesticides when mixing/loading, applying, or re-entering an area treated with a pesticide, treatment facility workers may be exposed to pesticides when handling treated wood and/or performing activities related to operating the treatment cylinder.

Thus, pesticides applied using treatment cylinders present challenges for risk assessment because limited data are available to estimate worker exposure. The Agency acknowledges these challenges and considered these and other factors when making its reregistration and risk management decisions.

B. Human Health Risk Assessment

EPA has conducted a human health risk assessment for wood preservative uses of creosote to support the reregistration eligibility decision. EPA evaluated the submitted toxicology, product and residue chemistry, and occupational/residential exposure studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision. However, confirmatory data are needed (see Section V). A summary of the human health findings and conclusions is presented below; the full risk assessments are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2003-0248.

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

1. Toxicity of Creosote

A brief overview of the toxicity studies used for determining endpoints in the risk assessments are outlined below in Table 3. Further details on the toxicity of creosote can be found in the Creosote*: Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision (RED) Document*, dated August 29, 2008. These documents are available on the U.S. Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2003-0248).

The Agency has reviewed all toxicity studies submitted to support guideline requirements for creosote and determined that the toxicological database is sufficient for reregistration. Major features of the toxicology profile are presented below.

a. Acute Toxicity

The acute toxicity database for creosote is considered complete. Both creosote P1/P13 and P2 fractions have a moderate order of acute toxicity in experimental animals via the oral and dermal routes (Toxicity Categories III). There are no acute inhalation concerns. However, P1/P13 causes substantial but temporary eye injury (Toxicity Category II) while P2 is moderately irritating to the eye (Toxicity Category III). Even though the dermal sensitization studies were unacceptable, it is assumed that both blends are dermal sensitizers. Tables 3 and 4 provide a summary of the two creosote fractions acute toxicity data.

Table 3. Acute Toxicity Data for Creosote P1/P13 Fraction

Guideline Number	Study Type	MRID Number	Results	Toxicity Category
870.1100 (81-1)	Acute Oral – Rat	43032101	LD_{50} Male = 2451 mg/kg Female = 1893 mg/kg	III
870.1200 (81-2)	Acute Dermal-Rabbit	43032102	LD_{50} > 2000 mg/kg	III
870.1300 (81-3)	Acute Inhalation-Rat	43032103	LC_{50} > 5 mg/L	IV
870.2400 (81-4)	Primary Eye Irritation –Rabbit	43032104	Irritation clearing in 8-21 days	II
870.2500 (81-5)	Primary Skin Irritation -Rabbit	43032105	Erythema to day 14	III
870.2600 (81-6)	Dermal Sensitiazation – Guinea Pig	43675301	Unacceptable	N/A

Table 4. Acute Toxicity Data for Creosote P2 Fraction				
Guideline Number	**Study Type**	**MRID Number**	**Results**	**Toxicity Category**
870.1100 (81-1)	Acute Oral – Rat	43032301	LD_{50} Male = 2524 mg/kg Female = 1993 mg/kg	III
870.1200 (81-2)	Acute Dermal-Rabbit	43032302	LD_{50} > 2000 mg/kg	III
870.1300 (81-3)	Acute Inhalation-Rat	43032303	LC_{50} > 5.3 mg/L	IV
870.2400 (81-4)	Primary Eye Irritation –Rabbit	43032304	Irritation clearing within 7 days	III
870.2500 (81-5)	Primary Skin Irritation -Rabbit	43032305	No irritation after 7 days	III
870.2500 (81-5)	Dermal Sensitiazation – Guinea Pig	43675201	Unacceptable	N/A

b. Toxicological Endpoints

On April 1, 1999, the Office of Pesticide Program's Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicological endpoints selected for occupational and residential (dermal and inhalation) exposure risk assessments for Creosote. On September 3, 2003, the OPP met to verify the selected endpoints for long-term dermal risk assessments for creosote and inhalation risk assessment, and also discussed whether dermal and inhalation Margins of Exposure should be combined for creosote risk assessment. The OPP held a final meeting on December 6, 2007, to discuss the quantitative carcinogenicity analysis performed on creosote by the Pest Management Regulatory Agency, Health Canada and to determine the appropriate potency factor for creosote. The toxicological endpoints selected for various exposure scenarios are summarized below in Table 5.

Table 5. Creosote Toxicological Endpoints			
Exposure Scenario	**Dose Used in Risk Assessment (mg/kg/day)**	**Target MOE, UF, Special FQPA SF* for Risk Assessment**	**Study and Toxicological Effects**
Acute and Chronic Dietary	These risk assessments are not required		
Cacinogenicity (dermal)	Creosote has been shown to exert positive mutagenic effects in vitro, and has been shown to be positive for carcinogenicity in an initiation/promotion study. Creosote has been classified as a B1 carcinogen in IRIS. An oral cancer slope factor of 6.28 x 10-6 (ug CTM1/kg/day)-1 was selected for creosote using the data of Culp et al (1998) for the coal tar mixture 1 (CTM1) on the basis of forestomach tumors.		
Short-Term Dermal	NOAEL (oral) = 50 mg/kg/day	FQPA SF = 1x MOE = 100 (10x inter-species extrapolation, 10x intra-species variation) (5% dermal absorption factor is used to correct for use of oral	Developmental Toxicity – Rat (MRID 43584201) LOAEL= 175 mg/kg/day, based on decreased body weight

Table 5. Creosote Toxicological Endpoints			
Exposure Scenario	**Dose Used in Risk Assessment (mg/kg/day)**	**Target MOE, UF, Special FQPA SF* for Risk Assessment**	**Study and Toxicological Effects**
		end point)	
Intermediate-term Dermal	NOAEL = 40 mg/kg/day	FQPA SF= 1x MOE = 100 (10x inter-species extrapolation, 10x intra-species variation)	90 Day Dermal Toxicity – Rat (MRID 43616201) LOAEL = 400 mg/kg/day based on decreased body weight gain
Long-Term Dermal	LOAEL = 25 mg/kg/day	FQPA SF = 1x MOE = 300 (10x inter-species extrapolation, 10x intra-species variation, and 3x for use of LOAEL)	2-generation reproduction – Rat LOAEL = 25 mg/kg/day based on decreased pre-mating body weight
Inhalation (any time period)	Creosote NOAEL = 0.0047 mg/m^3	FQPA SF =1x MOE= 100 (10x inter-species, 10x intraspecies)	90 day Inhalation Study-Rat (MRID 43600901) Based on decreased body weight gain, altered hematology
	Naphthalene[c] HEC = 52 mg/m^3 [NOTE: see Section 2.0 above	FQPA SF = 1x MOE = 300 (10x inter-species, 10x intra-species, and 3x for use of LOAEL)	Two year inhalation toxicity – mouse Based on nasal effects: hyperplasia and metaplasia in respiratory and olfactory epithelium, respectively
Dermal absorption	5% determined from the results of in vivo/ in vitro testing in rats and in vitro testing using human skin. (MRID 47179501 and 47179502)		

After re-examination of the toxicology data, the Agency concluded that the 2-generation reproduction toxicity study was appropriate for long-term dermal risk assessment because the duration of the 2-generation reproduction study is representative of the time frame for worker exposure to creosote at a wood treatment facility(i.e. long-term). In addition, body weight gain decreases in the 2-generation reproduction toxicity study were observed in the F2 generation, supporting the time frame for the long-term endpoint (i.e. > 6 months). The creosote database also includes a 90-day dermal study. The effects of this study are not considered representative of the time frame needed for the long-term dermal risk assessment. However, the two studies can be considered co-critical studies for this endpoint. Correction of the LOAEL from the 2-generation reproduction toxicity study for dermal absorption (5%) and use of a LOAEL (3x extra UF) yields a MOE and endpoint (300 and 50 mg/kg/day) similar to the 90-day dermal toxicity study (40 mg/kg/day and MOE of 300 [extra 3x to extrapolate to long-term endpoint]).

The Agency re-examined the use of the inhalation toxicity study (MRID 43600901) selected for inhalation risk assessment for creosote and concluded that a developmental toxicity study, as used for the oral and dermal risk assessments of creosote, is not appropriate for inhalation risk assessment because: (1) the inhalation toxicity study showed significant effects on body weight gain early in the study (one week) and is therefore relevant for short-term assessment (2) it is also a route-specific study; and (3) the inhalation NOAEL is more sensitive than the developmental NOAEL. Therefore, the Agency will rely on the inhalation study for the short-term inhalation endpoint. In addition, the dermal absorption of creosote was determined from submitted in vivo and in vitro studies on creosote (MRIDs 47179501 and 47179502).

Creosote has been shown to exert positive mutagenic effects in vitro, and has been shown to be positive for carcinogenicity in an initiation/promotion study. Creosote has been classified as a B1 carcinogen in the Integrated Risk Information System (IRIS). An oral cancer slope factor of 6.28×10^{-6} $(\mu g\ CTM1/kg/day)^{-1}$ was selected for creosote using the data of Culp et al (1998) for the coal tar mixture 1 (CTM1) on the basis of forestomach tumors.

2. Special Sensitivity

There are no existing food uses for creosote, therefore, an FQPA assessment is not necessary. Potential post-application exposures to residents, including children (e.g., from use of railroad ties by homeowners), could not be assessed due to lack of exposure data. The available evidence on developmental and reproductive effects of creosote was assessed by the Agency on April 1, 1999. The Health Effects Division (HED) Hazard Identification Assessment Review committee expressed concern about potential infant's and children's susceptibility, based on the severity of offspring vs. maternal effects observed with testing the P1/P13 blend of creosote in the developmental toxicity study in rats at the 175 mg/kg/day dose level as well as deficiencies observed in the 2-generation reproduction toxicity study in rats. Therefore, a 3x uncertainty factor was applied to the long-term dermal endpoint.

3. Exposure Assessment and Characterization

a. Dietary Exposure

There is no dietary exposure to creosote residues through food based on its classification as a restricted use pesticide and limited use pattern as a heavy duty wood preservative. Due to the restricted use pattern, it has been determined that creosote will not impact water resources. Therefore, dietary and drinking water risk assessments were not performed.

b. Residential Exposure and Risk Estimates

As a restricted use pesticide that all also requires highly specialized application equipment, creosote is neither permitted to be purchased nor expected to be applied by potential residential users. Therefore, residential exposure is not expected from the wood preservative uses of creosote and a residential risk assessment was not performed.

The Agency recognizes that materials such as utility poles or railroad ties may be sold for reuse after their original intended use has ended. These materials are often sold into a secondary market where they may be installed in residential settings for garden borders, etc. Because the lifespan of these treated materials is fairly long, the Agency believes that the creosote leaching from the treated material is significantly less than when it was originally placed into service.

However, the Agency has no data to conduct a risk assessment of these secondary uses of creosote-treated materials. Further evaluation of the potential risks and benefits associated with these secondary uses of creosote-treated materials will be conducted during the Registration Review process for this active ingredient.

c. Aggregate Risk Estimates

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

Based on creosote’s restricted use classification, the Agency has determined that there is no potential for human exposure to creosote through food and /or drinking water. Residential exposures to creosote residues may occur from secondary use of treated materials; however, there is no data available to assess these risks. Therefore, an aggregate risk assessment was not performed.

d. Occupational Exposure and Risk Estimates

Application of creosote, a restricted use pesticide, is limited to occupational handlers only. The restricted use classification mandates that only certified applicators or someone under direct supervision can handler/apply this pesticide; therefore, this chemical is not available for sale or use by homeowners. Prior to 2003, creosote was approved for non-pressure and pressure treatment uses. Effective December, 2004, creosote registrants voluntarily cancelled non-pressure treatment products and uses. Creosote applications are now restricted to pressure treatment only. For additional information, on occupational exposures to creosote, please see “Occupational Exposure Chapter for Creosote in Support of the Reregistration Eligibility Decision (RED) Document for the Creosote” dated September 5, 2008. These documents are available on the U.S. Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2003-0248).

Because creosote is currently registered for use in occupational settings, occupational handlers have the potential to be exposed through mixing, loading, or applying the pesticide and through handling the treated wood. These exposures could result in potential cancer and non-cancer risks. Therefore, EPA estimated cancer and non-cancer risks to occupational handlers as a result of inhalation and dermal exposure to creosote from products. EPA performed these assessments for individuals working at treatment facilities.

This document presents information summarized from the document entitled, "Occupational Exposure Chapter for Creosote in Support of the Reregistration Eligibility Decision (RED) Document for the Creosote" dated August 28, 2008. The summary information presented in this document demonstrates the estimated risks for creosote in general exceed EPA's levels of concern and, consequently, must be managed through mitigation and associated label changes (see Section IV of this document).

To estimate potential risks, the Agency developed dermal and inhalation exposure scenarios. For non-cancer risk estimates, these include short-term (1 day to 1 month), intermediate-term (1 to 6 months), and long-term (> 6 months) exposure durations. For cancer risk estimates, these include only lifetime exposure duration (working for 35 years).

For worker risk estimates, naphthalene was selected as an indicator because of analytical difficulties encountered with the coal tar pitch volatiles (CTPV) samples and because all of the naphthalene inhalation samples monitored at the pressure treatment facilities were detectable. However, the Agency is aware of recent developments regarding potential species differences in toxicity of naphthalene. *"Critical research has been published indicating that metabolic activation is a required step for naphthalene's respiratory toxicity (unmetabolized naphthalene is not the cause of the cytotoxicity or tumors) and that there are notable species differences in the metabolism of naphthalene between rodents and primates (Buckpitt et al. 1992, 1995, 2002; Bogen et al. 2008). Available research to date indicates that the metabolism pathway in rodents is more active than in humans (i.e., humans have a slower rate of formation of the active metabolite) (Buckpitt et al. 1992, 1995, 2002; Bogen et al. 2008)."*

Recognizing that rodents may be more susceptible to the toxic effects of naphthalene, but that the issue of human relevance is not fully scientifically resolved, the Agency has, at this time, based its creosote inhalation risk assessments for occupational workers on the LOAEL of 52 mg/m^3 selected from the naphthalene 2-year toxicity study in mice (NTP, 1992), as discussed in the Agency's IRIS Toxicological Review for naphthalene (http://www.epa.gov/ncea/iris/toxreviews/0436-tr.pdf). Other reasons for using naphthalene at this time are based on several significant deficiencies in the inhalation monitoring study conducted on creosote workers, including (1) no attempt by the study sponsors to relate inhalation levels found for polynuclear aromatics (PNAs) and coal tar pitch volatiles (CTPVs) to "total creosote" -- a significant weakness with the study; (2) analytical problems encountered with the CTPV samples (all samples were non-detect); and (3) the overall inhalation field fortification percent recoveries for the coal tar pitch volatiles (CTPVS) were poor (51-57%). It is understood that as further research is conducted with regard to the species differences in naphthalene disposition and toxicity, that the occupational inhalation assessment would be modified accordingly.

Significant exposure is not expected due to mixing/loading because treatment plants utilize automated methods for chemical preservative delivery (metered feed/pump) and closed application techniques (treatment cylinder). However, there is the potential for workers near the treatment cylinder door to inhale treatment solution mist when the door is opened following treatment and/or to contact treatment solution residue on equipment such as charge cables and the treated wood itself. Although in many cases treated wood is moved mechanically (e.g., forklifts), there are other activities such as removing bridge rails or retrieving charge cables that are performed by hand.

For treatment facility exposure scenarios, where possible, EPA estimated risk for each job function that could be performed at a typical treatment facility. Table 6 provides a summary of worker exposure scenarios at pressure treatment facilities submitted by the Creosote Council II (Creosote Council II, 2001). Although an effort was made to differentiate risk estimates by job function, the Agency acknowledges that in the studies used to estimate exposure, one person often performed more than one job function. Therefore, estimated risks presented for any single job function may overestimate exposure and risk because that individual may have performed multiple job functions during the exposure study.

Table 6: Job Descriptions of Workers Exposed at Pressure Treatment Facilities

Job Function	Description of worker activities	Monitoring Events		
		Site	Dermal	Inhalation
Treatment Operator TO (engineer)	Operates and manages the treatment system; may open and close cylinder doors; cleans accumulated creosote from doors and latches; operates valves to transfer creosote solution between holding tanks and treatment cylinders; handles leads and bands.	 A B C D	total: 18 4, 1/day 4, 1/day 5, 1/day 5, 1/day	total: 14 0 4, 1/day 5, 1/day 5, 1/day
Treatment Assistant TA (helper)	Performs and assists with tasks of the TO; charge preparation, cylinder cleaning, maintenance, filter cleaning, mixing treatment solution; loader operation and movement of charges.	B	total: 4 4, 1/day	total: 4 4, 1/day
Oil unloader OU	Operates creosote tank car unloading and transfer system; takes samples from tank cars; inserts siphons into tanks. (At site C, the tasks for this position were performed by the TO; position was not monitored at Site B)	 A D	total: 9 4, 1/day 5, 1/day	total: 5 0 5, 1/day
Loader Operator CLO (cylinder area) LLO (load out area)	Operates self-propelled vehicles for loading wood on and off trams, moving charges in and out of cylinders, and to and from load out areas. Out-of-cab tasks include tram placement, and handling chains and leads.	CLO A B C D	total: 18 4, 1/day 4, 1/day 5, 1/day 5, 1/day	total: 14 0 4, 1/day 5, 1/day 5, 1/day
		LLO B C D	total: 19 4, 1/day 5, 1/day 10, 2/day	total: 19 4, 1/day 5, 1/day 10, 2/day
Loader helper	Assists the LO in some tasks; works mainly on the drip pad and		total: 14	total: 14

Job Function	Description of worker activities	Monitoring Events		
		Site	Dermal	Inhalation
CH; LH	load out area, placing and removing charge leads, opening and closing cylinder doors, retrieving leads, adjusting track switches, and banding and unbanding charges.	B C D	4 LH, 1/d 5 CH, 1/d 5 CH, 1/d	4 LH, 1/d 5 CH, 1/d 5 CH, 1/d
Checker CK	Performed tasks of the loader helper as well as inspecting treated lumber. Worker part time in the treatment area.	 C	total: 5 5 CH, 1/d	total: 5 5 CH, 1/d
Test Borer/QC Person TB	Takes core samples to test for creosote penetration; may test creosote solution concentration (site C); other QC laboratory duties. (These tasks performed by CLO at site B)	 A C	total: 9 4, 1/day 5, 1/day	total: 5 0 5, 1/day
Water Treatment System Operator WO	Operates chemical/biological water recovery equipment (At Site C, the tasks associated with this position were performed by the TB; position not monitored at Site D)	 A B	total: 8 4, 1/day 4, 1/day	total: 4 0 4, 1/day
Drip pad cleaner DP	Steam-cleans drip pad area; disposes of sludge and treated wood waste; other cleanup duties in treatment and drip pad area.	 C	total: 4 4, 1/day	total: 4 4, 1/day
Total			108	88

The aforementioned worker exposure study provided chemical specific handler dermal and inhalation exposure data from four typical commercial treatment facilities in the U.S. and Canada, per the requirements of the U.S. Environmental Protection Agency, Canada's Pesticide Management Regulatory Agency (PMRA), and the California Department of Pesticide. The four sites include older facilities from the 1940s as well as more modern facilities with additional engineering controls. Therefore, the exposure and risk estimates have been presented separately for each site. The job functions monitored in the study are presented in Table 4 above.

There is an overall variability in the composition of creosote (e.g. over 100 known chemicals are components of creosote) which makes it difficult to characterize its exact nature. Since neither the characterization of airborne creosote nor the development of inhalation sampling methods is specific for creosote, there exists a high variability in the creosote inhalation data presented in literature. The Creosote Council study is the most recent study that assessed both dermal and inhalation exposure from creosote. This study provides the best available data on worker exposure estimates and encompasses all of the worker activities contributing to exposure.

i. Occupational Non-Cancer Risks

The Agency estimated the non-cancer effects as a result of inhalation and dermal exposure to creosote from creosote wood preservatives. Occupational non-cancer risk estimates are presented as Margins of Exposure (MOE). EPA's level of concern for non-cancer risks depends on the scenarios assessed.

a. Inhalation Non-Cancer Risk Estimates

The non cancer inhalation MOEs for worker exposure to naphthalene range from 23 to 1,900 with a target MOE of 300. Sixteen of the 19 inhalation MOEs presented exceed the target MOE of 300, and therefore, are of concern. Therefore, the risks presented in Table 7 maybe an overestimate of the actual risk as discussed above. However, these risks are presented as a conservative estimate to indicate the need for inhalation exposure mitigation.

Table 7. Inhalation MOEs for Naphthalene

Job	Site	n=	Site Description	Average Naphth (ug/m^3)	Average Naphth (mg/m^3)	% of TLV	MOE (Target = 300)
TO	A	4	1940s; manual	NA	NA	NA	NA
	B	4	1983; Eng. Controls	221	0.221	0.4	235
	C	5	1940s	1320	1.32	2.5	39
	D	5	1970s; Automated	802	0.802	1.5	65
TA	B	4	1983; Eng. Controls	406	0.406	0.8	128
OU	A	4	1940s; manual	NA	NA	NA	NA
	D	5	1970s; Automated	925	0.925	1.8	56
CLO	A	4	1940s; manual	NA	NA	NA	NA
	B	4	1983; Eng. Controls	227	0.227	0.4	229
	C	5	1940s	2033	2.033	3.9	26
	D	5	1970s; Automated	574	0.574	1.1	91
LLO	B	4	1983; Eng. Controls	27	0.027	0.1	1926
	C	5	1940s	694	0.694	1.3	75
	D	10	1970s; Automated	195	0.195	0.4	267
LLO(F)	D		1970s; Automated	679	0.679	1.3	77
LH	B	4	1983; Eng. Controls	43	0.043	0.1	1209
	C	5	1940s	1870	1.87	3.6	28
	D	5	1970s; Automated	2251	2.251	4.3	23
CK	C	5	1940s	117	0.117	0.2	444
TB	A	4	1940s; manual	NA	NA	NA	NA
	C	5	1940s	853	0.853	1.6	61
WO	A	4	1940s; manual	NA	NA	NA	NA
	B	4	1983; Eng. Controls	917	0.917	1.8	57
DP	C	4	1940s	347	0.347	0.7	150

TLV = 10 ppm (52 mg/m^3) STEL 15 ppm (79 mg/m^3)
mg/m^3 = ug/m3 / 1000
% of TLV = (mg/m^3 / 52) x 100
MOE = HEC / air conc; Where HEC = 52 mg/m^3.

b. Dermal Non-Cancer Risk Estimates

The results indicate the short-term (ST) non cancer dermal MOEs do not trigger potential risk concerns except for the treatment operator at site C where the dermal MOE is 68 and the target MOE is 100. The intermediate-term (IT) non cancer dermal MOEs trigger potential risk concerns for 8 of the 24 scenarios presented. Intermediate-term MOEs range from 3 to 2,700 with the target MOE of 100. The long-term (LT) non cancer dermal MOEs trigger potential risk concerns for 3 of the 24 scenarios. The long-term MOEs range from 34 to 34,000 where the target MOE is 300. The Agency notes that intermediate-term risk estimates being greater than LT risk estimates is an anomaly. However, in the case of creosote it is explained by the fact that IT toxicity endpoint is based on a dermal study while the LT endpoint is based on an oral study (i.e., there are differences in routes of exposure and dosing levels between the two studies). A dermal non-cancer risk summary is presented in Table 8 below.

Table 8. Creosote Dermal MOEs

Job	Site	n=	Site Description	Potential dermal dose (mg/kg/day)	Absorbed Dermal Dose (mg/kg/day)	Dermal MOEs ST	IT	LT
TO	A	4	1940s; manual	0.414	0.021	2415	97	1208
	B	4	1983; Eng. Controls	0.015	0.001	67568	2703	33784
	C	5	1940s	14.800	0.740	68	3	34
	D	5	1970s; Automated	0.132	0.007	7576	303	3788
TA	B	4	1983; Eng. Controls	0.025	0.001	40323	1613	20161
OU	A	4	1940s; manual	0.887	0.044	1127	45	564
	D	5	1970s; Automated	0.938	0.047	1066	43	533
CLO	A	4	1940s; manual	0.212	0.011	4717	189	2358
	B	4	1983; Eng. Controls	0.089	0.004	11299	452	5650
	C	5	1940s	2.120	0.106	472	19	236
	D	5	1970s; Automated	0.117	0.006	8547	342	4274
LLO	B	4	1983; Eng. Controls	0.018	0.001	55249	2210	27624
	C	5	1940s	0.203	0.010	4926	197	2463
	D	10	1970s; Automated	0.077	0.004	12953	518	6477
LLO(F)	D		1970s; Automated	0.244	0.012	4098	164	2049
LH	B	4	1983; Eng. Controls	0.023	0.001	43860	1754	21930
	C	5	1940s	1.810	0.091	552	22	276
	D	5	1970s; Automated	0.383	0.019	2611	104	1305
CK	C	5	1940s	0.822	0.041	1217	49	608
TB	A	4	1940s; manual	0.112	0.006	8929	357	4464
	C	5	1940s	1.060	0.053	943	38	472
WO	A	4	1940s; manual	0.204	0.010	4902	196	2451
	B	4	1983; Eng. Controls	0.047	0.002	21322	853	10661
DP	C	4	1940s	0.150	0.008	6667	267	3333

Site A,B,C,D indicate differences in site setup (e.g., eng controls).
Dermal exposures are not normalized to the various amount of wood treated.
Arithmetic mean of the dermal dose from Table 9 of the PMRA worker study review.
Abs Dermal Dose (mg/kg/day) = dermal dose (mg/kg/day) x 5% dermal absorption
Where ST NOAEL is 50 mg/kg/day (Target MOE = 100) and LT LOAEL is 25 mg/kg/day (Target MOE = 300).
Where IT NOAEL is 40 mg/kg/day (Target MOE = 100) from a dermal study.

ii. Cancer Risk Summary

The Agency estimated the probably of developing cancer as a result of inhalation and dermal exposure to creosote. Occupational cancer risk estimates are presented as a probability of developing cancer (e.g., one-in-a-million or 1 x 10^{-6}). In general, EPA's level of concern for cancer risk is 1 x 10^{-6}.

All of the cancer risk estimates for creosote exceed the Agency's level of concern; however, only 4 of the scenarios exceed 1 x 10^{-4}. A summary of the cancer risk estimates are presented in Table 9 below.

Table 9. Creosote Dermal Cancer Risk Estimates

Job	Site	n=	Site Description	Potential dermal dose (mg/kg/day)	Abs Dermal Dose (mg/kg/day)	Abs LADD (mg/kg/day)	Creosote Risk
TO	A	4	1940s; manual	0.414	0.0207	0.0071	4.5E-05
	B	4	1983; Eng. Controls	0.0148	0.0007	0.0003	1.6E-06
	C	5	1940s	14.8	0.7400	0.2534	1.6E-03
	D	5	1970s; Automated	0.132	0.0066	0.0023	1.4E-05
TA	B	4	1983; Eng. Controls	0.0248	0.0012	0.0004	2.7E-06
OU	A	4	1940s; manual	0.887	0.0444	0.0152	9.5E-05
	D	5	1970s; Automated	0.938	0.0469	0.0161	1.0E-04
CLO	A	4	1940s; manual	0.212	0.0106	0.0036	2.3E-05
	B	4	1983; Eng. Controls	0.0885	0.0044	0.0015	9.5E-06
	C	5	1940s	2.12	0.1060	0.0363	2.3E-04
	D	5	1970s; Automated	0.117	0.0059	0.0020	1.3E-05
LLO	B	4	1983; Eng. Controls	0.0181	0.0009	0.0003	1.9E-06
	C	5	1940s	0.203	0.0102	0.0035	2.2E-05
	D	10	1970s; Automated	0.0772	0.0039	0.0013	8.3E-06
LLO(F)	D		1970s; Automated	0.244	0.0122	0.0042	2.6E-05
LH	B	4	1983; Eng. Controls	0.0228	0.0011	0.0004	2.5E-06
	C	5	1940s	1.81	0.0905	0.0310	1.9E-04
	D	5	1970s; Automated	0.383	0.0192	0.0066	4.1E-05
CK	C	5	1940s	0.822	0.0411	0.0141	8.8E-05
TB	A	4	1940s; manual	0.112	0.0056	0.0019	1.2E-05
	C	5	1940s	1.06	0.0530	0.0182	1.1E-04
WO	A	4	1940s; manual	0.204	0.0102	0.0035	2.2E-05
	B	4	1983; Eng. Controls	0.0469	0.0023	0.0008	5.0E-06
DP	C	4	1940s	0.15	0.0075	0.0026	1.6E-05

Site A,B,C,D indicate differences in site setup (e.g., eng controls)
Dermal exposure not normalized to various amounts of wood treated per site
Arithmetic mean from Table 9 of the PMRA review.
Abs Dermal Dose (mg/kg/day) = dermal dose (mg/kg/day) x 5% dermal abs
Creosote Risk = LADD (mg/kg/day) x creosote oral CSF of 6.28E-3 $(mg/kg/day)^{-1}$

e. Post-Application Occupational Exposure

There is the potential for post-application exposures to creosote. Potential post-application exposure may occur as a result of creosote treated wood in commercial, industrial, and residential settings. There is the potential for contact with creosote treated wood for occupational workers who install railroad ties and poles. Railroad workers may become exposed during the mechanical and manual installation of pressure treated railroad crossties as well as during inspection procedures (ATSDR, 1990). Utility pole installers may also contact creosote treated wood while attaching fittings on treated poles, installing new utility poles, conducting ground line treatment of utility poles, and maintaining and repairing existing utility poles (ATSDR, 1990). No dermal exposure data were available for these scenarios. Mechanical installation and/or the use of specified PPE are needed to reduce exposure/contact with creosote treated wood.

Although there are no creosote label registered uses of creosote for residential uses, EPA acknowledges that some creosote treated wood such as railroad ties are used outdoors in home landscaping. The potential dermal and incidental oral exposures to outdoor landscape timbers are expected to be episodic in nature. During the public comment period of this risk assessment, comments were received by EPA suggesting the need for wipe studies to assess dermal and incidental oral exposure to children contacting creosote treated landscape ties. EPA has considered the potential magnitude of potential concerns for children by reviewing the CCA SHEDS assessment that was developed for arsenic exposure to treated lumber. In the CCA assessment, children are exposed to play sets and decks specifically built for contact by children. For creosote, frequency, activity, and duration of exposure to landscape ties around the home is believed to be episodic and of short duration when contact occurs. Based on this type of comparison, EPA does not believe a SHEDS-type of an assessment for creosote treated ties used as landscape timbers is warranted.

f. Human Incident Data

Creosote and creosote-containing substances are widely used in industry and by certain subgroups of individuals, resulting in a large population of persons with potential exposure. According to California data, the majority of poisoning incident cases occurred as a result of handling creosote and applying it to wood without proper protection for the skin and eyes. The number of these cases has dropped quite markedly in the 1990s. Substantial contact with treated wood appears to be a risk factor for skin and eye burns, even years after the wood was treated. Symptoms experienced were burns and rashes on the exposed body areas, chemical conjunctivitis, headaches, nausea, and eye irritation.

While a number of human health studies are available that include creosote as a possible, or even likely, target exposure, few studies are available with enough information for a rigorous assessment of chronic health effects attributable to creosote specifically. By far, the most common limitation of studies aimed at evaluating effects of creosote exposure is the almost total absence of objective exposure measurements for the study participants. For most of the studies, assessment of exposure is based on information about past occupational activities provided by the participants or assigned by health studies professionals such as industrial hygienists with general knowledge of occupations and materials. In almost all cases, possible exposure to other materials, either separately or concomitantly, cannot be excluded. A second important limitation often seen in studies on effects of creosote is the lack of statistical significance calculated for many of the apparent associations between assigned creosote exposure and development of disease.

These limitations notwithstanding, among the epidemiological studies on effects of creosote exposure, increased risks for development of a number of diseases have been observed. Diseases typically found to be in excess include skin cancer and nonmalignant skin disorders, bladder cancer, lung cancer and nonmalignant respiratory diseases. Considering the information presently available, conclusions regarding chronic health effects from exposure to creosote alone should be considered tentative.

B. Environmental Risk Assessment

Creosote is registered as a preservative to protect wood from fungi, insects, and marine-boring organisms. Products are applied commercially by pressurized treatment to dry wood intended for exterior/outdoor uses only. These uses include railroad cross ties and treated timbers for track and bridge construction; electric and utility utility poles; and pilings for freshwater and marine docking, seawall structures, and subsurface foundation support for buildings. According to American Wood Preserver’s Association, nearly all railroad crossties, switch ties, and bridge timbers, and about 15% of all utility poles are pressure treated with creosote.

Environmental exposure levels from wood preservative applications may be a concern for aquatic and terrestrial nontarget organisms exposed to leachate or runoff.

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks and ecological hazards for creosote. For detailed discussions of all aspects of the environmental risk assessment, see Environmental Fate and Transport Assessment of Creosote for the Reregistration Eligibility Decision (RED) Process, dated September 11, 2008 and Revised Ecological Risk Assessment for Creosote dated August 28, 2008. These documents are available on the U.S. Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2003-0248).

1. Environmental Fate and Transport

The Agency considered the P1/P13 and P2 fractions of coal tar creosote for this fate and transport assessment. These fractions are obtained from the distillated collected between 210 ^{o} C and 355 ^{o} C. Primary use of these fractions (henceforth called creosote) is for wood preservation and is applied to railroad ties and utility poles. The environmental fate and transport risk assessment for creosote is complicated by the following factors: 1) creosote is a mixture of 200-250 identifiable substances; 2) of these, 85% are polyaromatic hydrocarbons (PAHs) and the rest are cyclic heteronuclear nitrogen and oxygen containing substances; PAHs constitute higher percent (mass) of the component mixture, these weigh heavily in the overall fate and risk assessment; 3) No guideline studies were submitted, therefore the Agency has relied heavily on the published literature studies; and 4) studies found in published literature were conducted under varying conditions. Therefore, uncertainties exist in the interpretations of study results.

PAHs in the creosote mixture are divided up into 3 distinct groups: PAHs with two fused aromatic rings, PAHs with 3 fused aromatic rings, and PAHs with 4 and 5 fused aromatic rings. A number of published studies focus and provide results and interpretations on these groups.

Most of the PAHs belonging to all three groups discussed above, are not water soluble and have no hydrolysable hydrogens and hence in water hydrolytic pathway for dissipation does not occur. A few PAHs like acenaphthene, fluorene, phenanthrene, anthracene and fluoranthene show a degree of volatility from wood surfaces. More volatility has been observed at higher temperature (30 ^{o} C) and less at lower temperatures (4 ^{0}C). As much as 85 percent PAHs still remain on the wood surface at lower temperatures. Half lives of volatility for these components are between 6 months to one year. Volatilization also does not appear to be a dissipation pathway for PAHs in the environment.

Since most of the PAHs are not water soluble, these undergo photo oxidation from surface water and photo oxidation half lives are short. Photo oxidation, therefore appears to be an important dissipation pathway for PAHs. However, the photo oxidized products are persistent in air, water and soils and are bioaccumulative.

Some of the PAHs on surface may partition (adsorb) into soils and sediments and those with 4-5 fused rings may stay longer with the sediments. Some of these may partition (desorbed) into water again.

A number of studies have shown that PAHs leach out from the creosote –treated utility and railroad ties at a higher rate initially but do not show a huge degree of vertical or downward migration into soils. Studies also indicate that most (85%) of the PAHs stay within the treated wood. One study on 200 US estuaries indicated that PAHs from creosote-treated decks, and bulkheads leached and preferably migrated to sediments that were muddy.

A more recent mesocosm study on creosote-treated railroad ties showed similar results: core samples of PAHs which leached out did not migrate beyond 60 cm. downward into the ballast, with amounts decreased progressively with distance. Similarly, only 1/16 samples collected from the storm water showed the presence of two PAHs: Benzo(a) anthracene (0.00019 mg/L) and phenanthrene (0.00066 mg/L).

A number of studies show that PAHs have a tendency to biodegrade in soils under aerobic conditions. Over 80% biodegradation takes place within the first month after the treated wood is in use. Benzo(a)pyrene and benzo(k)fluoranthene showed resistance to biodegradation. One study showed that due to the rapid depletion of oxygen under aerobic conditions, anaerobic biodegradation of PAHs can take place due to denitrifying, sulfate-reducing, and methanogenic bacteria.

Many studies have shown that photo oxidized products of PAHs on surface water and surface soils are persistent and bioaccumulative and adversely affect the aquatic biota, and organisms in soils and sediments.

A number of studies have indicated that in aquatic medium, fish, shellfish, and crustaceans bioaccumulate PAHs readily. It has been shown that *Daphnia pulex* bioaccumulates PAHs like naphthalene, anthracene, phenanthrene, pyrene, 9-methyl anthracene, benz(a)anthracene, and perylene. Clams (Rangia cuneate0 has been shown to bioaccumulate PAHs such as naphthalene, biphenyl/acenaphthylene, fluorene, phenanthrene/anthracene/chrysene and benzopyrene.

A study conducted in the Great Lakes on Zebra Mussels showed that pre-spawning species bioaccumulates benzo(a)pyrene much faster than does the post-spawning species.

A few studies also indicate PAHs with a higher number of fused rings will partition to those soils /sediments with a high K_{oc} values. Hence these PAHs will not be bioavailable to the benthic organisms. However, if the PAHs have a high K_{OW} value, then the Kow will counter the impact of Koc and these PAHs can become bioavailable

Based on calculations and modeling, it appears that half lives of PAHs in the environmental media like water, soils and sediments follow this trend: half lives of

PAHs with 2 fused aromatic rings < PAHs with 3 fused aromatic rings < PAHs with 4-5 fused aromatic rings. In general, half lives in air and water are lower than in soils or sediments. In addition, PAHs with two fused aromatic rings have log Kow values between 3 and 4, PAHs with 3 and 4 used aromatic fused rings have log Kow values between 4and 5 and PAHs with 5 fused aromatic ring have log Kow values of 6 and above. Hence it appears that PAHs with 4-5 fused aromatic rings will be more likely to be persistent in water, soils, and sediments and bioaccumulative to the benthic organisms. However these PAHs also absorb to the soils and sediments very tightly, hence these may not be bioavailable to the benthic organisms.

2. Ecological Effects

The toxicity endpoints typically used in ecological assessments are obtained from guideline toxicity studies conducted for wildlife, aquatic organisms, and plants (40 CFR §158.2060). Guideline studies are required for all pesticides to provide acute and chronic measures of effect for one or more test species in several taxonomic groups. As noted in the 2003 preliminary ecological risk assessment, guideline toxicity studies are not available for creosote. The preliminary assessment relied on the whole creosote data available in the open literature, but insufficient data were obtained to assess chronic effects to freshwater invertebrates or to marine/estuarine aquatic organisms. For the updated assessment, available acute and chronic toxicity information for the PAHs has been obtained from the open literature, including relevant laboratory, microcosm, and field studies obtained through ECOTOX searches and other sources, including EPA Sediment Quality Criteria documents for fluoranthene (EPA 1993a), phenanthrene (EPA 1993b), and acenaphthene (EPA 1993c).   For additional information, please see the Ecological Risk Assessment for Creosote, dated August 28, 2008.   This document is available on the U.S. Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2003-0248).

a. Wildlife and Plant Toxicity

The Agency has concluded that there is minimal risk of exposure to birds, terrestrial mammals, and terrestrial plants from creosote due to leachate or runoff from treated materials.

b. Aquatic Toxicity

i. Acute Toxicity

The level of concern (LOC) is exceeded for acute risk to listed (i.e., endangered and threatened) freshwater and saltwater (estuarine/marine) fish and aquatic invertebrates as well as nonlisted saltwater invertebrates exposed to PAHs in the water column and/or aquatic sediment. Table 10 presents the PAHs that are highly to very highly toxic to freshwater and saltwater fish and invertebrates, with anthracene and fluoranthene being the most toxic PAHs in the water column.

Table 10. Acute Toxicity of Creosote PAHs to Aquatic Organism in the Water Column

PAH/ media[a]	Species	Exposure duration (h)	LC50/EC50 (µg/L)	Source
Anthracene				
SW	Fish - no data			
	Mysid shrimp	48	3.6	Pelletier 1997
FW	Bluegill (*Lepomis macrochirus*)	96	1.27	McCloskey 1991
	Scud (*Hyalella azteca*)	240	5.6	Hatch 1999
Fluoranthene				
SW	Sheepshead minnow	96	0.8	EPA 1993b
	Mysid shrimp	96	0.58	Spehar 1999
FW	Fathead minnow	96	6.8	Diamond 1995
	Water flea	48	0.97	Spehar 1999
Acenaphthene				
SW	Sheepshead minnow	96	2200	Heitmuller 1981
	Mysid shrimp	96	160	EPA 1993c
FW	Brown trout (*Salmo trutta*)	96	580	Holcombe 1983
	Stone fly (*Tallaperla maria*)	96	240	Horn 1983
Fluorene				
SW	Fish - no data			
	Polychaete worm	96	1000	Rossi 1978
FW	Bluegill	96	760	Mayer 1986
	Water flea	48	420	
Naphthelene				
SW	Sheepshead minnow	24	2400	Anderson 1974
	Humpy shrimp (*Pandalus goniurus*)	96	971	Korn 1979
FW	Pink salmon (*Oncorhyncus gorbuscha*)	96	890	Rice 1989
	Water flea (*Daphnia pulex*)	96	1000	Trucco 1983
Chrysene				
SW	Fish - no data			
	Polychaete worm (*Neanthes arenaceodentata*)	96	<1000	Rossi 1978
FW	Fish - no data			
	Water flea	20	1900	Kagan et al.1987
Pyrene				
SW	Fish - no data			
	Opossum shrimp (*Americamysis bahia*)	48	0.89	Pelletier et al. 1997

PAH/ media[a]	Species	Exposure duration (h)	LC50/EC50 (µg/L)	Source
FW	Fathead minnow	3.2	25.6	Oris 1987
	Water flea	2	4	Kagan et al. 1987
Phenanthrene				
SW	Atlantic silverside (*Menidia menidia*)	96	108	EPA 1993a
	Mysid shrimp	96	17.7	
FW	Bluegill	96	234	EPA 1993a
	Hydra (*Hydra* sp.)	96	96	

[a] SW = saltwater; FW = freshwater

ii. Chronic Toxicity

There were no guideline chronic toxicity studies available to assess the chronic risks of PAHs. However, the available data indicates that chronic risk (survival, growth, reproduction, immunotoxicity) is possible to aquatic organisms inhabiting the water column. Table 11 presents the adverse effects of fluoranthene, acenaphthene, and phenanthrene on fish and invertebrates.

Table 11 Chronic Toxicity of Creosote PAHs on Aquatic Organisms in the Water Column

PAH/ media[a]	Species	NOEC/LOEC (µg/L)	Effect	Source
Fluoranthene				
SW	Fish - no data			
	Mysid	11.1 / 18.8	survival, reproduction	Champlin and Poucher 1991
FW	Fathead minnow	10.4 / 21.7	survival, growth	Brooke 1991
	Daphnia magna	10.6 / 21.2	growth	Brooke 1992
Acenaphthene				
SW	Fathead minnow	332 / 495	growth	Cairns and Nebeker 1982
	Mysid (*M. bahia*)	44.6 / 91.8	reproduction	Thursby et al. 1989
FW	Sheepshead minnow	520 / 970	survival	Ward et al. 1981
	Midge (*Paratanytarsus* sp.)	295 / 575	egg hatching	NAS 1982
Phenanthrene				
SW	Fish - no data			
	Mysid	5.5 / 11.9	survival	Kuhn and Lussier 1987
FW	Rainbow trout	5 / 8	survival	Call et al. 1986
	Daphnia magna	57 / 163	reproduction, survival	

c. Risk Characterization

Based on the existing laboratory and field data and modeling of PAH aquatic concentrations from use of creosote-treated railroad ties and aquatic structures, the Agency has assessed the risks to freshwater and saltwater fish and invertebrates exposed in the water column and/or in aquatic sediment. These findings are presented below.

i. Acute Risks

When a new creosote-treated wood structure is installed in an aquatic environment, there is an immediate release of creosote components into the water column. During their study in the Sooke Basin, Goyette and Brooks (1998) report that creosote leaching from the portions of aquatic pilings above the water line initially forms a sheen on the water surface. They speculated that microdroplets from the surface sheen subsequently move down through the water column and into the sediment, with little of that creosote dissolving in the water column. However, they did not measure water-column concentrations until 6 months after pilings (dolphins) were installed in Sooke Basin. Ingram et al. (1982) and Bestari et al. (1998) measured PAH concentrations in the water column in the initial days and weeks and found levels that might be of concern for exposure of aquatic organisms.

Acute RQs for aquatic organisms exposed to the PAH component expected in the water column are presented in Table 12. The weighted acute toxicity values used to calculate RQs for the total PAH component are as follows:

Freshwater fish weighted LC50 = 405 µg/L
Freshwater invertebrate weighted EC50 = 267 µg/L
Saltwater fish weighted LC50 = 1150 µg/L
Saltwater invertebrate weighted EC50 or LC50 = 399 µg/L

Table 12. Acute RQs for Exposure of Aquatic Organisms to PAHs in the Water Column

Site	Time after initial exposure	Freshwater[a]		Estuarine/Marine[a]	
		Fish	Invert.	Fish	Invert.
300-gal tanks; seawater (Ingram et al.1982)	72 hr	n/a	n/a	**0.37***	**1.08****
	12 day	n/a	n/a	**0.13***	**0.39***
1200-L outdoor microcosms; freshwater (Bestari et al.1998)	7 day	**0.24***	**0.36***	n/a	n/a
	3 mo.	0.02	0.02	<0.01	0.02
Sooke Basin; marine (Goyette and Brooks 1998)	6 mo.	n/a	n/a	<0.01	<0.01
Railroad (wet scenario)	0 hr	**0.77****	**1.16****	**0.27***	**0.78****
	96 hr	**0.45***	**0.69****	**0.16***	**0.46***
	21-day avg.	**0.23***	**0.35***	**0.08***	**0.24***
	60-day avg.	**0.15***	**0.22***	**0.05***	**0.15***
	90-day avg.	**0.13***	**0.20***	0.04	**0.13***
Railroad (dry scenario)	0 hr	**0.12***	**0.18***	0.04	**0.12***
	96 hr	**0.07***	**0.11***	0.02	**0.07***
	21-day avg.	0.03	0.04	<0.01	0.03
	60-day avg.	0.01	0.02	<0.01	0.01
	90-day avg.	<0.01	0.01	<0.01	<0.01

[a] based on weighted toxicity values: FW fish = 405 ppb; FW invertebrate = 267 ppb; SW fish = 1150 ppb; SW invertebrate = 399 ppb

** exceeds the acute LOC for non-listed species (RQ $\geq$0.5) and listed species (RQ $\geq$0.05)

* exceeds the acute LOC for listed species

The RQs determined for Sooke Basin do not exceed the Agency's acute LOC; however, those concentrations were measured 6 months after pilings were installed and may simply represent background PAH concentrations. Based on the total PAH concentrations reported in seawater by Ingram et al. (1982) and in freshwater by Bestari et al. (1998) and the weighted toxicity values, the acute LOC is exceeded for listed fish and aquatic invertebrates. The acute LOC also is exceeded for non-listed estuarine/marine invertebrates. Exceedance of an LOC indicates a potential for adverse effects on nontarget organisms and identifies a need for regulatory action to mitigate risk (Appendix B).

Based on the EECs modeled for railroad structures, the acute LOC for listed freshwater and saltwater species is exceeded in wet areas (MS scenario). Exposure levels of concern potentially exist for several months. Non-listed species are at potential risk for the acute, and short-term. In drier areas (CA scenario), the acute LOC is only exceeded for listed species and only in the short-term.

Zooplankton communities may be at acute risk. Comparing the 5-day EC50 of 44.6 µg/L for community-level effects to the aquatic EECs (Tables 3 and 5), indicates that the LOC would potentially be exceeded 1- to 10-fold for acute risks due to creosote leaching from aquatic structures and railroad structures.

ii. Chronic Risks

Insufficient data exist to calculate weighted toxicity values for the PAH component; therefore, chronic RQs are not calculated. However, comparing EECs to the available data (previously presented in the Toxicity Data section) indicate that adverse affects on survival, growth, and/or reproduction could be expected in some situations (Table 13). The potential for chronic risk is presumed in OPP risk assessments when the chronic EEC (21-day-avg. for invertebrates and 60-day-avg. for fish) exceeds the NOEC. Chronic exposure in the water column potentially poses risks to fish and/or aquatic invertebrates around aquatic structures and, especially in wetter areas, where leachate from railroad structures may move into the aquatic environment.

Table 13. EECs and Adverse Effects from Chronic Exposure in the Water Column

<table>
<tr><th>Site</th><th>EEC (µg/L)</th><th>Reported effect
concentrations (µg/L)</th></tr>
<tr><td>300-g SW tanks</td><td>156 (12 d)</td><td rowspan="4">0.4-1.0 (salmon, herring; development)
0.61 (rainbow trout; immunotoxicty)
9 (herring; hatching sig. reduced)
44.6 (zooplankton; community EC50)
30-50 (invertebrates; survival, brood size)
5-57 (phenanthrene NOECs[a])
10-11 (fluoranthene NOECs[a])
44-520 (acenapthene NOECs[a])</td></tr>
<tr><td>12,000-L FW microcosms</td><td>0.8-6.7 (84 d)</td></tr>
<tr><td>Railroad
(wet scenario)</td><td>94.4 (21-d-avg.)
59.3 (60-d-avg.)</td></tr>
<tr><td>Railroad
(dry scenario)</td><td>11.4 (21-d-avg.)
5.0 (60-d-avg.)</td></tr>
</table>

[a] NOECs based on survival, growth, and reproduction

3. Risk to Listed Species

Section 7 of the Endangered Species Act (ESA), 16 U.S.C. Section 1536(a)(2), requires that federal agencies consult with the National Marine Fisheries Service (NMFS) for marine and andronomus listed species, or with the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if 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 is to "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 comply with subsection (a)(2) of the ESA, EPA's Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly appreciably reduce 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). If any of the Listed Species LOC Criteria are exceeded for either direct or indirect effects in the Agency's screening-level risk assessment, the Agency identifies any listed or candidate species that may occur spatially and temporally in the footprint of the proposed use. Further biological assessment is undertaken to refine risk estimates. The extent to which any species may be at risk determines the need to develop a more comprehensive consultation package as required by the ESA.

The ecological risk assessment for creosote indicates a potential for exposure of listed fish and aquatic invertebrate species that warrants a more refined assessment to include direct, indirect, and habitat effects. The refined assessment should involve clear delineation of the action area associated with proposed use of creosote 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. An endangered species effect determination will not be made at this time.

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 creosote 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 products containing creosote.

The Agency has completed its assessment of occupational and ecological risks associated with the use of pesticide products containing the active ingredient creosote. The Agency has determined that all creosote containing products are eligible for reregistration provided that: 1) all risk mitigation measures are implemented; 2) current data gaps and confirmatory data requirements are satisfied; and 3) label amendments are made as described in Section V. Appendix A summarizes the uses of creosote 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 creosote 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 creosote, the Agency has determined that creosote 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 creosote. If all conditions and requirements outlined in this document are fully complied with, then no risks of concern would exist for the registered uses of creosote 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.

1. Regulatory Rationale

The Agency has determined that wood preservative uses of creosote are eligible for reregistration provided that the registrants implement the conditions and requirements in this RED including the amended labeling and the requirements for additional data. With amended labeling, EPA believes that the uses presented in Appendix A will not present risks inconsistent with FIFRA and that the benefits of creosote to society outweigh the remaining risks. A summary of EPA's rationale for reregistering and managing risks associated with continued use is presented below.

a. Summary of Risks

As discussed in Section III of this document, EPA acknowledges the complexity and uncertainities associated with assessing potential risks from pesticides applied using treatment cylinders. Therefore, the risk estimates presented in this document may be overestimated. Notwithstanding, EPA has identified the following potential risks of concern associated with the continued use of wood preservatives containing creosote.

- Occupational cancer and non-cancer risk estimates from inhalation exposure to creosote
- Occupational cancer and non-cancer risk estimates from dermal exposure to creosote

Without the adoption of additional protective measures to reduce exposure, continued use would not meet the “no unreasonable adverse effects” criteria of FIFRA.

b. Summary of Benefits and Alternatives

A detailed discussion of creosote benefits and alternatives is presented in the document entitled, “REVISED: A Qualitative Economic Impact Assessment of the Use of Alternatives to Creosote as a Wood Preservative” dated September 25, 2008.

i. Alternatives

Creosote is used to treat lumber, crossties, switch and bridge ties, timbers, pilings, and poles. 99% of the US market of wood treated railroad crossties, bridge, and switch ties are treated with creosote. Chemical alternatives to creosote wood preservatives include pentachlorophenol, chromated arsenicals, ammoniacal copper zinc arsenate (ACZA), and copper HDO. Non-chemical alternatives include concrete, composite, steal, fiberglass-reinforced composite, laminated wood, and plastic.

Chemical and non-chemical alternatives vary in efficacy. In many cases, efficacy is the determining factor for selecting the preservative and/or material used. For example, creosote treated crossties offer lower mass and greater resiliency which results in a more resilient tract with improved dynamic attenuation or impact loading. It also improves the track component life and improves ride quality by reduction in noise and vibration. Creosote treated wood ties also provide electrical isolation properties which minimizes electrical leakages into ties that could disrupt signal systems. In contrast, there is no chemical alternative for creosote and certain non-chemical alternatives are known to pose installation challenges due to weight as well as premature degradation. They are also known to cause electrical leakages resulting in signal disruptions.

In the short-term, a product treated with an alternative preservative may offer comparable efficacy compared to a product treated with creosote; however, comparable efficacy may or may not be observed over the entire expected lifespan of the product (e.g., a marine pilings may require replacement much sooner than if it had been treated with creosote). Because certain alternatives do not offer the same level of efficacy and because the end products themselves (e.g., marine pilings) may not last as long as creosote, they also cannot be considered as direct replacements.

Finally, economic considerations almost always impact decisions regarding project materials. Included in economic considerations are initial costs (e.g., cost of wood treatment), lifespan and maintenance costs of the product, and disposal costs. Although many exceptions exist, creosote generally offers lower initial costs than many alternatives, offer documented and predictable lifespan, and in many cases can be disposed of in municipal landfills. Because certain alternatives, although lower in initial costs, do not offer the same resistance and/or do not last as long as creosote treated products, they also cannot be considered as direct replacements. Economic considerations are particularly relevant to railroads and other public works uses because increased costs are frequently passed on to the public.

c. Risk Benefit Finding

In its risk assessments, EPA identified potential risks of concern for workers exposed to creosote at wood treatment plants. Notwithstanding, eliminating these uses could result in reliance on products with greater safety risks, reduced effectiveness, and higher costs could be passed on to the general public. Therefore, EPA has determined that the wood preservative uses of creosote will not pose unreasonable risks to humans or environment provided that (1) all risk mitigation measures are implemented, (2) label amendments are made as described in Section V, and (3) current data gaps and confirmatory data requirements are satisfied.

2. Endocrine Disruptor Effects

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

3. Cumulative Risks

Risks summarized in this document are those that result only from the use of creosote. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides, for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to creosote.

EPA has not assumed that creosote share a common mechanism of toxicity with other compounds.

4. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decision for creosote. During the 60-day pubic comment period ending on June 16, 2008, the Agency received comments on the revised risk assessments from seven respondents: Creosote Council, Beyond Pesticides, California Regional Water Quality Board, Northwest Coalition for Alternative to Pesticides, Treated Wood Council, Association of American Railroads, and Utility Solid Waste Activities Group. All comments and EPA's official responses are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2003-0248.

B. Risk Management Decision

The Agency has concluded that continued use of wood preservatives containing creosote would not meet the "no unreasonable adverse effects" criteria of FIFRA, unless the mitigation measures and associated label changes presented in Table 13 and 14, respectively, are implemented and confirmatory data submitted. Information is not currently available to quantify the amount of potential risk reduction; however, implementing these potential risk reduction measures will reduce worker exposure to creosote. The Agency will require confirmatory monitoring data to ensure that the measures set forth below are protective.

Although the measures below are deemed necessary at this time, in the future, registrants may request that EPA remove or reduce certain restrictions or mitigation measures upon submission of acceptable toxicity and exposure studies that demonstrate to the Agency that risk exposures to creosote are below EPA's level of concern.

Table 13. Creosote Mitigation Measures

Potential Risks of Concern	Mitigation Measure(s)	Required Label Language
Occupational cancer and non-cancer risk estimates from inhalation exposure to creosote	After treatment, personnel must not be located within 15 feet of the cylinder opening until the cylinder is ventilated and the door is completely open	"At the conclusion of the treatment, the cylinder must be ventilated by purging the post-treatment cylinder through fresh air exchange. The ventilation process is considered complete after a minimum of 2 volume exchanges based on the empty treatment cylinder volume. The exhaust pipe of the vacuum system or any air moving device utilized in conducting the air purge must terminate into a containment vessel such as a treating solution work tank or water/effluent tank. The ventilation process may be accomplished by one of the following

Potential Risks of Concern	**Mitigation Measure(s)**	**Required Label Language**
		methods: 1) activating an air purge system that operates while the cylinder door remains closed; or 2) using a device to open and hold open the cylinder door (no more than 6 inches) to allow adequate ventilation and activating the vacuum pump. If the second method is utilized, at the conclusion of the treatment, no personnel may be located within 15 feet of the cylinder when open (cracked) until the cylinder has been ventilated. In the event of equipment malfunction, or to place the spacer to hold the door open during venting, only personnel wearing specified PPE are permitted within 15 feet of the cylinder opening prior to ventilation. After ventilation is complete, the cylinder door may be completely opened."
Occupational cancer and non-cancer risk estimates from dermal exposure to creosote	The treatment process must include a final vacuum to remove excess preservative from the wood	"The treatment process must include a final vacuum to remove excess preservative from the wood. The final vacuum must attain a vacuum equal to or greater than the initial vacuum. This vacuum must be held for an appropriate time period based on wood species, retention levels, and commodity treated to remove excess preservative from the wood."
	Automatic opening, closing, and locking devices	"As of December 31, 2013, for elevated temperature pressure treatment with creosote, automatic, remotely operated devices must be used to open, close, lock, and unlock cylinder doors."
	Allow excess preservative to drain before removing charges from the treatment cylinder and prior to shipment	"After treatment, wood must be moved to a drip pad capable of recovering excess preservative until the wood is drip free."
	Personnel must wear personal protective equipment when handling treated wood/equipment, when cleaning the cylinder,	"All personnel handling treated wood or handling treating equipment (including poles/hooks used to retrieve charge cables) that has come in contact with preservative must wear the following PPE: * washable or disposable coveralls or long-

Potential Risks of Concern	Mitigation Measure(s)	Required Label Language
Occupational cancer and non-cancer risk estimates from dermal exposure to creosote	and approaching cylinder prior to ventilation	sleeved shirt and long pants, * chemical resistant gloves, and * socks plus industrial grade safety work boots with chemical resistant soles. All personnel cleaning or maintaining the treatment cylinder gasket/equipment or working with concentrate or wood treatment preservative must wear the following PPE: * washable or disposable coveralls or long-sleeved shirt and long pants, * chemical resistant gloves, * socks plus industrial grade safety work boots with chemical resistant soles, and * a full face shield. In the event of equipment malfunction, or for door spacer placement, all personnel located within 15 feet of the cylinder opening prior to cylinder ventilation must wear the following PPE: * washable or disposable coveralls over long-sleeved shirt and long pants, * chemical resistant gloves, * socks plus industrial grade safety work boots with chemical resistant soles, and * a properly fitting half mask elastomeric respirator with appropriate cartridges and/or filters. Entry to confined spaces is regulated by Federal and/or State Occupational Safety and Health Programs. Compliance is mandated by law. Individuals who enter pressure treatment cylinders or other related equipment that is contaminated with the wood treatment preservative (e.g.,cylinders that are not free of the treatment preservative or preservative storage tanks) must wear protective clothing and/or equipment as required by Federal and/or State Occupational Safety and Health Compliance laws.”
Occupational cancer and non-cancer risks from dermal exposure to creosote	Cylinder openings and door pits	“Cylinder openings and door pits must use grating and additional measures such as sumps, dams or other devices which prevent or remove spillage of the preservative.”

Potential Risks of Concern	Mitigation Measure(s)	Required Label Language
	Personnel must not retrieve charge cables by hand	"Personnel must not directly handle the charge cables, poles or hooks used to retrieve charge cables, or other equipment that has contacted the preservative without wearing chemical resistant gloves."
	Personnel must not place or remove bridge rails by hand	"As of December 31, 2013, mechanical methods must be used to place/remove bridge rails."
	Personnel must not eat, drink, or smoke in work areas	"Eating, drinking, and smoking is prohibited in the treatment cylinder load-out area, drip pad area, and engineering control room of wood treatment facilities." EXCEPTION: Where treating operator control rooms are isolated from the treating cylinders, drip pad, and work tanks, eating, drinking, and smoking (depending on local restrictions) are permitted."
	Work clothing must be left at the treatment facility	"Personnel must leave aprons, protective coveralls, chemical resistant gloves, work footwear, and any other material contaminated with preservative at the treatment facility."
Aquatic organisms acute and chronic risk estimates from exposure to creosote	Double vacuum for wood used in aquatic and other sensitive environments	"For treated wood that will be used in marine or other aquatic or sensitive environments, a double vacuum must be used. Following the pressure period and once the creosote has been pumped back to the work tank, a vacuum shall be applied for a minimum of one and a half hours at not less than 22 inches of Hg (560 KPa) (adjusted for elevation) of vacuum to recover excess preservative. Then, depending on plant equipment: 1) vacuum for a minimum of one and a half hours at not less than 22 inches of Hg (560 KPa) (adjusted for elevation); or 2) steam material for one hour minimum and then pull not less than 22 inches of Hg (560 KPa) (adjusted for elevation) vacuum for a minimum of one and a half hours. Maximum temperature during steaming shall not exceed 240 degrees F (115.5 degrees C), as specified in the Best Management Practices (Aug. 2006) issued by the Western Wood Preservers Association, Southern Pressure Treaters' Association, Timber Piling Council, and Wood Preservation Canada."

C. Management of Creosote-treated Materials

The Agency is aware that materials such as utility poles or railroad ties may be sold for reuse after their original intended use has ended. The typical lifespan for a utility pole or railroad tie is approximately 10 to 30 years, depending on climate, setting and other factors. These materials are often sold into a secondary market where they may be installed in residential settings for garden borders, etc. Because the lifespan of these treated materials is fairly long, the Agency believes that the creosote leaching from the treated material is significantly less than when it was originally placed into service. The Agency has not conducted a risk assessment of these secondary uses of creosote-treated materials but has begun to evaluate these uses and has found that other options such as disposing of these materials in a landfill, or incinerating these materials for energy generation are also currently practiced. Further evaluation of the potential risks and benefits associated with these secondary uses of creosote-treated materials will be conducted during the Registration Review for this active ingredient.

1. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information is specified to included in the labeling of all end-use products containing creosote For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that creosote is eligible for reregistration provided that: (i) the additional data that the Agency intends to require to confirm this decision are submitted; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 8). The additional data requirements that the Agency will require will include, among other things, submission of the following:

A. Manufacturing Use Products

1. Generic Data Requirements

The generic database supporting the reregistration of creosote has been reviewed and determined to be substantially complete to support a reregistration eligibility decision. However, the data requirements listed in Tables 14 and 15 below have been identified by the Agency as confirmatory and will be included in the generic DCI for this RED. Specific deadlines are set forth in the generic data call-in (GDCI), including those for submission of initial responses and/or requests for time extensions or data waivers as well as for other required steps.

Surrogate dermal and inhalation and submitted unit exposure values were taken from the proprietary Chemical Manufacturer's Association (CMA) antimicrobial exposure study (US EPA 1999: DP Barcode D247642). Most of the CMA data are of poor quality and therefore, the Agency requires that confirmatory monitoring data be generated and submitted to support the values used in the occupational and residential risk assessments and to further refine these assessments. The required confirmatory monitoring data are listed in Table 14 below.

Table 14. Confirmatory Guideline Studies for Creosote

Guideline Study Name	New OPPTS Guideline Number
Occupational Exposure Confirmatory Data	
Dermal Outdoor Exposure	875.1100
Dermal Indoor Exposure	875.1200
Inhalation Outdoor Exposure	875.1300
Inhalation Indoor Exposure	875.1400
Applicator Exposure Monitoring Data Reporting	875.1600
Product Use Information	875.1700
Environmental Fate & Ecological Exposure Confirmatory Data	
Field Study or simulated study for aquatic structures, sediment concentration data for cool northern conditions, and water column concentrations from microcosm studies	850.1950
Leaching Study for release of creosote components from creosote impregnated wood	Non-Guideline

The following ecotoxicity guideline studies have not been adequately addressed by the open literature. Depending on the outcome of any field or simulated field studies, some or all of the studies listed below may be needed further refine the risk assessment for listed and nonlisted species. They are reserved pending results of the field or simulated field studies.

Table 15. Reserved Guideline Studies for Creosote

Guideline Study Name	New OPPTS Guideline Number
Environmental Fate & Ecological Exposure Confirmatory Data	
Freshwater invertebrate acute toxicity	850.1010
Freshwater fish acute toxicity	850.1075
Estuarine/marine fish acute study	850.1075
Estuarine/marine shrimp acute study	850.1035
Estuarine/marine mollusk acute study	850.1025
Aquatic invertebrate (freshwater) life-cycle study	850.1300
Fish early life-stage (freshwater) study	850.1400
Aquatic invertebrate (estuarine/marine) life-cycle study	850.1300
Fish early life-stage (estuarine/marine) study	850.1400
Whole sediment: acute freshwater invertebrates	850.1735
Whole sediment: acute marine invertebrates	850.1740
Whole sediment: chronic invertebrates	No guideline no.
Freshwater diatom	850.5400
Marine diatom	850.5400

Guideline Study Name	New OPPTS Guideline Number
Blue-green cyanobacteria	850.5400
Freshwater green alga	850.5400
Freshwater floating macrophyte duckweek	850.4400
Freshwater rooted macrophyte rice seedling emergence	850.4225
Freshwater rooted macrophyte rice vegetative vigor	850.4250

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

1. Completed response forms to the GDCI (i.e., GDCI 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 the deadline specific 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 Jacqueline Campbell-McFarlane at (703) 308-6416 with questions regarding generic reregistration.

By US mail:

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

B. End-Use Products

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

The PDCI will set forth specific deadlines, including how to complete and submit response forms or requests for time extensions and/or waivers as well as product-specific data.

For end-use products containing the active ingredient creosote, the registrants are required 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) 308-6341 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:

Document Processing Desk
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

2. Labeling for Manufacturing and End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language to incorporate these changes is presented in Table 16. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific 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.

To ensure compliance with FIFRA, technical and manufacturing-use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies and also bear the labeling contained in Table 16, 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 creosote RED. The following table describes how language on the labels should be amended.

Table 16. Required Label Changes for Manufacturing and End-Use Wood Preservative Products Containing Creosote

Description	Creosote: Required Labeling Language	Placement on Label
Manufacturing-Use Products		
For all Manufacturing Use Products	"Only for formulation as a preservative for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and PR Notice 93-10 and 95-1	"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 have 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

Description	Creosote: Required Labeling Language	Placement on Label
End-Use Products		
PPE Requirements Established by the RED	"Personal Protective Equipment (PPE)" "All personnel handling treated wood or handling treating equipment (including poles/hooks used to retrieve charge cables) that has come in contact with preservative must wear the following PPE: * washable or disposable coveralls or long-sleeved shirt and long pants, * chemical resistant gloves, and * socks plus industrial grade safety work boots with chemical resistant soles. All personnel cleaning or maintaining the treatment cylinder gasket/equipment or working with concentrate or wood treatment preservative must wear the following PPE: * washable or disposable coveralls or long-sleeved shirt and long pants, * chemical resistant gloves, * socks plus industrial grade safety work boots with chemical resistant soles, and * a full face shield. In the event of equipment malfunction, or for door spacer placement, all personnel located within 15 feet of the cylinder opening prior to cylinder ventilation must wear the following PPE: * washable or disposable coveralls over long-sleeved shirt and long pants, * chemical resistant gloves, * socks plus industrial grade safety work boots with chemical resistant soles, and * a properly fitting half mask elastomeric respirator with appropriate cartridges and/or filters. Entry to confined spaces is regulated by Federal and/or State Occupational Safety and Health Programs. Compliance is mandated by law. Individuals who enter pressure treatment cylinders or other related equipment that is contaminated with the wood treatment preservative (e.g., cylinders that are not free of the treatment preservative or preservative storage tanks) must wear protective clothing and/or equipment as required by Federal and/or State Occupational Safety and Health Compliance laws."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Creosote: Required Labeling Language	Placement on Label
PPE Requirements Established by the RED	**P1/P13 formulations**: Warning. Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eye wear (goggles, safety glasses, or faceshield). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. **P2 Formulations**: Caution. Causes moderate eye irritation. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eye wear (goggles, safety glasses, or faceshield). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.	Precautionary Statements
User Safety Requirement	"Personnel must leave aprons, protective coveralls, chemical resistant gloves, work footwear, and any other material contaminated with preservative at the treatment facility." "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them." "Eating, drinking, and smoking are prohibited in the treatment cylinder load-out area, drip pad area, and engineering control room of the wood treatment facilities." EXCEPTION: Where treating operator control rooms are isolated from the treating cylinders, drip pad, and work tanks, eating, drinking, and smoking (depending on local restrictions) are permitted."	Precautionary Statements: Hazards to Humans and Domestic Animals Immediately following the PPE requirements

Description	Creosote: Required Labeling Language	Placement on Label
User Safety Recommendations	"USER SAFETY RECOMMENDATIONS" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Description	Creosote: Required Labeling Language	Placement on Label
Other Application Restrictions (Risk Mitigation)	"At the conclusion of the treatment, the cylinder must be ventilated by purging the post-treatment cylinder through fresh air exchange. The ventilation process is considered complete after a minimum of 2 volume exchanges based on the empty treatment cylinder volume. The exhaust pipe of the vacuum system or any air moving device utilized in conducting the air purge must terminate into a containment vessel such as a treating solution work tank or water/effluent tank. The ventilation process may be accomplished by one of the following methods: 1) activating an air purge system that operates while the cylinder door remains closed; or 2) using a device to open and hold open the cylinder door (no more than 6 inches) to allow adequate ventilation and activating the vacuum pump. If the second method is utilized, at the conclusion of the treatment, no personnel may be located within 15 feet of the cylinder when open (cracked) until the cylinder has been ventilated. In the event of equipment malfunction, or to place the spacer to hold the door open during venting, only personnel wearing specified PPE are permitted within 15 feet of the cylinder opening prior to ventilation. After ventilation is complete, the cylinder door may be completely opened."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"After treatment, wood must be moved to a drip pad capable of recovering excess preservative until the wood is drip free."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"The treatment process must include a final vacuum to remove excess preservative from the wood. The final vacuum must attain a vacuum equal to or greater than the initial vacuum. This vacuum must be held for an appropriate time period based on wood species, retention levels, and commodity treated to remove excess preservative from the wood."	Directions for Use

Description	Creosote: Required Labeling Language	Placement on Label
Other Application Restrictions (Risk Mitigation)	"For treated wood that will be used in marine or other aquatic or sensitive environments, a double vacuum must be used. Following the pressure period and once the creosote has been pumped back to the work tank, a vacuum shall be applied for a minimum of one and a half hours at not less than 22 inches of Hg (560 KPa) (adjusted for elevation) of vacuum to recover excess preservative. Then, depending on plant equipment: 1) vacuum for a minimum of one and a half hours at not less than 22 inches of Hg (560 KPa) (adjusted for elevation); or 2) steam material for one hour minimum and then pull not less than 22 inches of Hg (560 KPa) (adjusted for elevation) vacuum for a minimum of one and a half hours. Maximum temperature during steaming shall not exceed 240 degrees F (115.5 degrees C), as specified in the Best Management Practices (Aug. 2006) issued by the Western Wood Preservers Association, Southern Pressure Treaters' Association, Timber Piling Council, and Wood Preservation Canada."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"As of December 31, 2013, for elevated temperature pressure treatment with creosote, automatic, remotely operated devices must be used to open, close, lock, and unlock cylinder doors."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"As of December 31, 2013, for ambient creosote treatments, an automatic locking/unlocking device must be used to accomplish locking and unlocking of the cylinder door."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"Cylinder openings and door pits must use grating and additional measures such as sumps, dams or other devices which prevent or remove spillage of the preservative."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"Personnel must not directly handle the charge cables, poles or hooks used to retrieve charge cables, or other equipment that has contacted the preservative without wearing chemical resistant gloves."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"As of December 31, 2013, mechanical methods must be used to place/remove bridge rails."	Directions for Use

Appendices

Appendix A: Creosote Use Patterns Eligible for Reregistration

Use Site	EPA Registrations	Method of Application	Application Rate/ No. of applications	Use Limitations
Wood preservatives				
Lumber, timber, poles, ties, marine pilings, and other wooden members, all exterior wood exposed to moisture or weather	363-14 363-15 61468-1 61468-3 61468-9 61470-1 73408-1 73408-2 363-48 61483-8 61483-9	Pressure Treatment	Use only dry wood. Unseasoned wood should first be steamed conditioned, followed by a 1 to 3 hour vacuum period by vapor drying., normal retention required for creosote is from 6 to 12 pounds per cubic foot Approx 100 ft^2/gallon	**Restricted use pesticide** (*Due to chronic toxicity in animal studies*) For use only by certified applicators or by persons under their direct supervision, and only for those uses covered by the certified applicators certification. For Exterior Use Only Do not use this product on wood intended for use in homes.
Groundline Treatment of Utility Poles	61483-11 61483-12	Pressure Treatment	Use only dry wood. Unseasoned wood should first be steamed conditioned, followed by a 1 to 3 hour vacuum period by vapor drying., normal retention required for creosote is from 6 to 12 pounds per cubic foot	

Use Site	EPA Registrations	Method of Application	Application Rate/ No. of applications	Use Limitations
Technical Chemical	61468-6	For formulation or repackaging wood preservative products for use in pressurized treatment only.		**Restricted use pesticide** (*Due to chronic toxicity in animal studies*) For use only by certified applicators or by persons under their direct supervision, and only for those uses covered by the certified applicators certification

APPENDIX B: Creosote (Case 0139)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Creosote. These requirements apply to Creosote 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. **(12)** **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

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		44141101
830.1600 830.1620 830.1650	61-2	Starting Materials and Manufacturing Process		41597801, 43804901
830.1700	62-1	Preliminary Analysis		44141104
830.1750	62-2	Certification of Limits		41597801, 43804901
830.1800	62-3	Analytical Method		44141101, 44141102, 44141103, 44141104, 44141105, 44141106
830.6300	63-0	Reports of Multiple phys/chem Characteristics		44141102, 44141103, 44141105, 44141106, Open Literature
830.6302	63-2	Color		Open Literature
830.6303	63-3	Physical State		46027001
830.6304	63-4	Odor		Open Literature
830.7220	63-6	Boiling Point		Open Literature
830.7300	63-7	Density		46027001
830.7840 830.7860	63-8	Solubility		Open Literature
830.7950	63-9	Vapor Pressure		Open Literature
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)		Open Literature
830.7000	63-12	pH		Open Literature
830.6313	63-13	Stability		Open Literature

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.6315	63-15	Flammability		Open Literature
830.6316	63-16	Explodability		Open Literature
830.6317	63-17	Storage Stability		44141103, 44141106, 45355601, 45355602, 45355701, 45355702, 45355801, 45355802, 45355901, 45356001, 45356002, 45356101, 45356102, 45356201, 45356202, 45363901, 45363902
830.6320	63-20	Corrosion Characteristics		45355601, 45355602, 45355701, 45355702, 45355801, 45355802, 45355901, 45356001, 45356002, 45356101, 45356102, 45356201, 45356202, 45363901, 45363902
ECOLOGICAL EFFECTS				
850.1950		Field Study or Simulated Study for Aquatic Structures, Sediment Concentration Data		Field studies requested
Non-Guideline		Leaching Study for Release of Creosote Components from Creosote Impregnated Wood		Field studies requested
850.1010	72-2	Acute Aquatic Invertebrate Toxicity		Reserved
850.1075	72-1	Fish Acute Toxicity – Freshwater (Rainbow Trout)		Reserved pending field studies
850.1300	72-4	Fish early life-stage testing-freshwater		Reserved pending field studies
850.1400	72-4b	Invertebrate life-cycle testing - freshwater		Reserved pending field studies
850.2100	71-1	Avian Acute Oral Toxicity Test (Quail/Duck)		Reserved pending field studies
850.4225	123-1	Seedling emergence dose-response in rice		Reserved pending field studies
850.4250	123-1	Vegetative vigor dose-response in rice		Reserved pending field studies
850.4400	123-2	Aquatic vascular plant dose-response toxicity		Reserved pending field studies

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.5400	123-2	Acute algal dose-response toxicity - 4 species		Reserved pending field studies
TOXICOLOGY*				
870.1100	81-1	Acute Oral - Rat		43032101, 43032301
870.1200	81-2	Acute Dermal - Rabbit		43032102, 43032302
870.1300	81-3	Acute Inhalation - Rat		43032103, 43032303
870.2400	81-4	Primary Eye Irritation - Rabbit		43032104, 43032304
870.2500	81-5	Primary Dermal Irritation - Rabbit		43032105, 43032305
870.2600	81-6	Dermal Sensitization		43675301 (Unacceptable Studies)
870.3250	82-3	90-Day Dermal-Rodent		43616101, 43616201
870.3465	82-4	28/90-Day Inhalation -Rat		43601001, 43600901
870.4100 870.6200	83-1	Chronic Toxicity		44844401
870.3700	83-3	Developmental Toxicity -Rat		43584201, 43584202, 44839802
870.3800	83-4	2-Generation Repro.-Rat		42893201
870.4200	83-2	Oncogenicity		44844401
Non-Guideline		Dermal Absorption		47179501, 47179502
Exposure				
Non-Guideline		Creosote Council Study		45323401

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket. The OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 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 docket initially contained the 10/28/2003 preliminary risk assessment and the related documents. EPA considered comments on these risk assessments (available in the public docket) and revised the risk assessments. The revised risk assessments and RED for creosote will be made available in the public docket.

All documents, in hard copy form, may be viewed in the OPP docket or downloaded or viewed via the Internet at www.regulations.gov (Docket ID #EPA-HQ-OPP-2003-0248).

These documents include:

- Creosote Revised Risk Assessment; Notice of Availability, 4/16/2008.

Revised Risk Assessment and Supporting Science Documents:

- Creosote: Preliminary Risk Assessment for the Reregistration Eligibility Decision, PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 3/31/08.
  Timothy F. McMahon, Ph.D., Norm Cook, Chief, A. Najm Shamim, PhD., William
  Erickson, Ph.D., Jonathan Chen, Ph.D., Timothy Leighton, Environmental Scientist.
- Product Chemistry Science Chapter on Creosote. PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 2/14/08 A. Najm Shamim, PhD.
- Creosote: Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document, PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 2/29/08, Timothy F. McMahon, Ph.D.
- Creosote Residue/ Dietary Risk Assessment (P1/P13 and P2 Fractions) for the Reregistration Eligibility Decision. PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 2/14/08, A. Najm Shamim, Ph.D.
- Creosote Occupational/Residential Exposure Assessment. PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 3/31/2008, Timothy Leighton, Ph.D.
- Epidemiology and Incidents Reports Associated with Creosote. Cases 0139, Antimicrobials Division, 3/9/08.
- Environmental Fate and Transport Assessment of Creosote for the Reregistration Eligibility Decision (RED). PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 2/14/08, A. Najm Shamim, Ph.D.
- A Qualitative Economic Impact Assessment on the Use Alternatives to Creosote as a Wood Preservative for the Reregistration Eligibility Decision (RED). PC

Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 4/14/2008 Jonathan Becker, Senior Science Advisor and Stephen Hopkins Environmental Protection Specialist.

- Ecological Hazard and Environmental Risk Assessment: Creosote. PC Codes 022003, 025003, and 025004, Case 0139 Antimicrobials Division, 3/7/08, William Erickson Ph.D.

Final Risk Assessment and Supporting Science Documents (RED Supporting Documents):

- Creosote: Risk Assessment for the Reregistration Eligibility Decision, PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 8/29/08. Timothy F. McMahon, Ph.D., Norm Cook, Chief, A. Najm Shamim, PhD., William Erickson, Ph.D., Jonathan Chen, Ph.D., Timothy Leighton, Environmental Scientist.
- Product Chemistry Science Chapter on Creosote. PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 2/14/08 A. Najm Shamim, PhD.
- Toxicology Disciplinary Science Chapter for the Reregistration Eligibility Decision Creosote. PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 8/29/08 Timothy F. McMahon, Ph.D.
- Creosote Residue/ Dietary Risk Assessment (P1/P13 and P2 Fractions) for the Reregistration Eligibility Decision. PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 2/14/08, A. Najm Shamim, Ph.D.
- Creosote Occupational/Residential Exposure Assessment. PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 9/5/2008, Timothy Leighton, Ph.D.
- Epidemiology and Incidents Reports Associated with Creosote. Cases 0139, Antimicrobials Division, 3/9/08.
- Environmental Fate and Transport Assessment of Creosote for the Reregistration Eligibility Decision (RED). PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 9/11/08, A. Najm Shamim, Ph.D.
- A Qualitative Economic Impact Assessment on the Use Alternatives to Creosote as a Wood Preservative for the Reregistration Eligibility Decision (RED). PC Codes 022003, 025003, and 025004, Case 0139, Antimicrobials Division, 4/14/2008 Jonathan Becker, Senior Science Advisor and Stephen Hopkins Environmental Protection Specialist.
- Creosote - Endpoint Selection Report. PC Code: 025004, 8/29/08 Timothy F. McMahon, Ph.D.
- Ecological Hazard and Environmental Risk Assessment: Creosote. PC Codes 022003, 025003, and 025004, Case 0139 Antimicrobials Division, 3/27/08, William Erickson Ph.D.

Appendix D. Citations Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

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

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

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

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

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

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

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

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

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

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

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

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

1. MRID Studies

MRID #	Citation
44141101	Wade, Terry L. 1992. Product Chemistry Methods Development and Validation for Creosote. Analysis and Certification of Product Ingredients: Aristech Creosote P1/P13. Pesticide Assessment Guidelines Reference Series 62. U.S.E.P.A. Pesticide Assessment Guidelines Subdivision D: Product Chemistry. Unpublished study prepared by Geochemical and Environmental Research Group, Texas A&M University, for Aristech Chemical Corporation and John H. Butala, Technical Advisor, Creosote Council II. July 23, 1992.
44141102	Wade, Terry L. 1992. Product Chemistry Methods Development and Validation for Creosote. American Wood Preservers Association (AWPA) Standard Physical Characteristics: Aristech Creosote P1/P13. AWPA Standard Methods for Analyses of Creosote and Oil-Type Preservatives (A1-89). U.S.E.P.A. Pesticide Assessment Guidelines Subdivision D: Product Chemistry. Unpublished study prepared by Geochemical and Environmental

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44141103 Wade, Terry L. 1992. Product Chemistry Methods Development and Validation for Creosote. Analyses of Physical and Chemical Characteristics: Aristech Creosote P1/P13. Pesticide Assessment Guidelines Reference Series 63. U.S.E.P.A. Pesticide Assessment Guidelines Subdivision D: Product Chemistry. Unpublished study prepared by Geochemical and Environmental Research Group, Texas A&M University, for Aristech Chemical Corporation and John H. Butala, Technical Advisor, Creosote Council II. September 15, 1992.

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43032301	North American P2 Creosote: Acute Oral Toxicity Study in Rats. Study conducted by IRDC, Mattawan, MI for the Creosote Council II. Unpublished. HED document no. 011033.
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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the *Creosote* RED for a list of data needs.

Appendix F. Product Specific Data Call-In

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

Appendix G. Batching of End-Use Products

The Agency intends to complete the batching for products containing creosote at a later date. This information will be included with the data call-in.

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

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

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

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/.

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

Instructions

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

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

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

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

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

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

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

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

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program—Storage and Disposal Statements

    b. 84-1 Clarification of Label Improvement Program

    c. 86-5 Standard Format for Data Submitted under FIFRA

    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

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

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

b. EPA Form No. 8570-4, Confidential Statement of Formula

c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

e. EPA Form No. 8570-35, Data Matrix

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

a. Registration Division Personnel Contact List

b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

c. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

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

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

   Date of receipt
   EPA identifying number
   Product Manager assignment

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

Agency concerning an application for registration, experimental use permit, or tolerance petition.

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