

262384
RECORD NO.

025004
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 4-10-90 OUT 5-30-90

FILE OR REG. NO 61

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 7-88

DATE RECEIVED BY EFED 4-6-90

RD REQUESTED COMPLETION DATE _____

EEB ESTIMATED COMPLETION DATE _____

RD ACTION CODE/TYPE OF REVIEW 350

TYPE PRODUCT(S) : I, D, H, F, N, R, S

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. E. Feris PM(74)

PRODUCT NAME(S) Coal Tar/Creosote

COMPANY NAME Creosote Council II

SUBMISSION PURPOSE Response to waiver request

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	& A.I.
<u>025004</u>	<u>Coal Tar/Creosote</u>	
_____	_____	_____
_____	_____	_____
_____	_____	_____



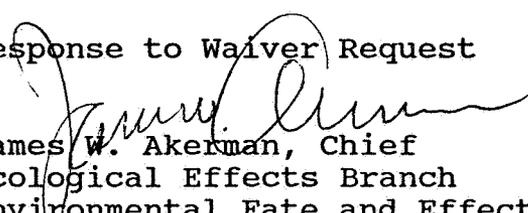
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 1 1999

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDIUM

SUBJECT: Response to Waiver Request

FROM: 
James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: E. Feris PM (74)
Special Registration and Reregistration
Registration Division (H7505C)

Ecological Effects Branch (EEB) has reviewed the registrant's justification for a waiver to support Creosote (P1/P13, and P2 fractions) registration based on domestic outdoor use pattern. We disagree that a waiver is in order for these fractions for the following reasons:

1. P1/P13, and P2 are new generic fractions;
2. EEB requires testing of each active ingredient in a product. In this case each active ingredient (P1/P13, and P2 fractions) are required;
3. EEB does not have data in it's files to determine the toxicity category for terrestrial wildlife species nor aquatic organisms; and
4. The proposed use pattern will allow for direct contact with water (e.g., piers, boat docks, piling etc.).

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Also, the Federal Register dated Wednesday October 24, 1984 under domestic outdoor use indicates all the previously required studies using P1/P13, and P2 fractions are required to support Creosote registration. The marine/estuarine studies are referred to as conditionally required. Since leaching of Creosote from treated wood in shallow waters may pose a hazard to aquatic organisms, Therefore, the marine/estuarine studies are required to support this registration.

The data requirement for both aquatic nonfood and domestic outdoor uses are the same (see attached table).

CONCURRENCES							
SYMBOL	H7507C	H7507C	H7507C				
SURNAME	Laird	Cook	Alger				
DATE	4-25-90	4-25-90	4/27/91				

Wednesday
October 24, 1984

Federal Register

Part II

**Environmental
Protection Agency**

**40 CFR Part 158
Data Requirements for Pesticide
Registration; Final Rule**

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Foilar dissipation.....	(1)	CR	CR	CR	CR			CR			TEP.....	TEP.....	132-1
Soil dissipation.....	(1), (4)	CR	CR	CR	CR			CR			TEP.....	TEP.....	132-1
Dermal exposure.....	(1), (2), (3)	CR	CR	CR	CR			CR			TEP.....	TEP.....	133-3
Inhalation exposure.....	(1), (2), (3)	CR	CR	CR	CR			CR			TEP.....	TEP.....	133-4

Key: CR=Conditionally required; TEP=Typical end-use product.
 (b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
 (1) Data are required if the following conditions are met:
 (A) The acute dermal toxicity of the technical grade of active ingredient is less than 200 mg/kg (body weight); or
 (B) The acute inhalation toxicity of the technical grade of active ingredient is less than 200 mg/m³ (for a one-hour exposure); or
 (C) The acute oral toxicity of the technical grade of active ingredient is less than 50 mg/kg (body weight); or
 (D) Neurotoxic, teratogenic, or oncogenic effects or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from entry of persons into treated sites; or
 (E) The Agency receives other scientifically validated toxicological or epidemiological evidence that a pesticide or residue of a pesticide could cause adverse effects on persons entering treated sites. In the last situation, reentry intervals and supporting data may be required on a case-by-case basis.
 (ii) And if: end-use product is to be registered for:
 (A) Application to growing crops, such as to or around horticultural and agronomic crops that are field- or orchard-grown.
 (B) Application to outdoor tree nursery and forestry operations.
 (C) Application to turf crops and commercial applications to turf.
 (D) Application to parks and arboretums; or (E) application to aquatic crops.
 (iii) And if: human exposure to residues of the pesticide can be reasonably foreseen. This applies primarily to pesticides that will be used on crops where human tasks will involve substantial exposure to residues of the pesticide.
 (2) Data required if appropriate surrogate data are not available.
 (3) Data required if the applicant chooses to use the allowable exposure level method for proposal of a reentry interval.
 (4) Soil dissipation data required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil.

(Approved by the Office of Management and Budget under control numbers 2000-0483 and 2000-0468.)

§ 158.142 Spray drift data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the aerial spray drift data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Droplet size spectrum.....	(1)	CR	CR	CR	CR			CR			TEP.....	TEP.....	201-1
Drift field evaluation.....	(1)	CR	CR	CR	CR			CR			TEP.....	TEP.....	202-1

Key: CR=Conditionally required; TEP=Typical end-use product.
 (b) NOTES.—The following are referenced in column two of the table contained in paragraph (a) of this section.
 (1) This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants. This requirement may be satisfied by submittal of published or unpublished information regarding spray drift patterns that would be expected to be similar to the proposed product.
 (2) [Reserved]

(Approved by the Office of Management and Budget under control numbers 2000-0483 and 2000-0468.)

§ 158.145 Wildlife and aquatic organisms data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the wildlife and aquatic organisms data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Avian and mammalian testing													
Avian oral LD ₅₀ (preferably mallard or bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI.....	TGAI.....	71-1
Avian dietary LC ₅₀ (preferably mallard and bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI.....	TGAI.....	71-2
Wild mammal toxicity.....	(2)	CR	CR	CR	CR			CR	CR		TGAI.....	TGAI.....	71-3
Avian reproduction (preferably mallard and bobwhite).	(3)	CR	CR	CR	CR			CR	CR		TGAI.....	TGAI.....	71-4
Simulated and actual field testing—mammals and birds.	(2)	CR	CR	CR	CR			CR	CR		TEP.....	TEP.....	71-5
Aquatic organism testing													
Freshwater fish LC ₅₀ (preferably rainbow and bluegill).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI.....	TGAI.....	72-1
Acute LC ₅₀ freshwater invertebrates (preferably Daphnia).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI.....	TGAI.....	72-2
Acute LC ₅₀ estuarine and marine organisms.	(4), (7)	CR	CR	CR	CR			CR	CR		TGAI.....	TGAI.....	72-3

10/18/89
Answer to S. Jackson
Formal Response of Agency
to Creosote Council
Sent to Council Not
Dated (maybe 4-00-1) but
Dated for Agency will be
emailed a Garbus memo.

025004

Agencies cover
memo reflects
the agency's position
on Coal Tar Creosote,
EPA's data require-
ments are now
for 2 rather than
3 test materials.

MEMORANDUM:

SUBJECT: Creosote: Response to Registration Standard and (see Data Call-In Notice of April, 1988. Request for Waiver of Product Chemistry Requirements attached for Manufacturing Use Products. RCB No. 4280 Data table

FROM: Joel Garbus, PhD., Chemist
Dietary Exposure Branch
Health Effects Division (TS-769c)

P1 and P13

THRU: Charles Trichilo, PhD., Chief
Dietary Exposure Branch
Health Effects Division (TS-769c)

are now
combined for
their respective
tests. P2 & P1
remains as we
initially req.

TO: L. Rossi / S. Jackson PM-21
Fungicide-Herbicide Branch
Registration Division (TS-767c)

2 id.

H.T. Cramer

The Creosote Council II, composed of companies in the creosote industry, has responded to Registration Standard and Data Call-In Notice for Pesticide Products Containing Coal Tar/Creosote as the Active Ingredient, issued April, 1988.

11/8/89

Among other concerns, the letter from the Creosote Council raises several issues that fall within the purview of the Dietary Exposure Branch. These are: the number and nature of the materials to be tested; the procedures most suitable for the characterization of complex mixtures; and product chemistry requirements for manufacturing-use products as listed in Table B of the Registration Standard.

The Number and Nature of the Materials to be Tested:

The Agency had agreed that the data required by the Registration Standard for each creosote product could be generated using an industry-wide composite sample. The Creosote Council II proposes to prepare 2 composite samples, P1/P13 and P2.

As regard to the number and nature of the materials to be tested, it has been the Agency's understanding that AWPA standards exist for 8 distinct creosote or creosote/tar products. The Agency, therefore, requested data for each of these products. The Creosote Council II states in its letter that it anticipates that all products other than P1/P13 and P2 will be voluntarily cancelled. As given in the Creosote Council II's submission, P1/P13 combines the specifications of P1, coal tar creosote for land and fresh water use with those of P/13, coal tar creosote for marine use (coastal waters). As the registration of P7, creosote for brush or spray treatment for cut fields, is to be canceled, the result is a single standard and, in essence, a single coal tar creosote composition that will be registered for all creosote uses for land and for fresh and marine waters.

Likewise, the proposed cancellation of the registration of creosote/coal tar solutions corresponding to the specifications of P12, the standard for creosote/coal tar solution to be used in the treatment of marine (coastal waters) piles and timbers and the continuing registration of one grade of P2 would result in only 1 registered creosote/coal tar solution. (The AWPA standard for P2 allows for 4 grades, A, B, C, and D of P2 depending upon the amount of coal tar in solution. This ranges from 20% for grade A to 50% for grade D. The submission of the Creosote Council II indicates that the P2 that will be continued in registration is grade C.)

The Creosote Council II is stating, in effect, that only one creosote standard solution will be registered and that only one creosote/coal tar standard solution will be registered.

The Agency will require confirmation from the creosote industry and from the AWPA that only two creosote formulations will be registered for use as pesticides before the Agency will consent to the creation of only two composite test materials for testing.

Chemical Characterization of Creosote and Creosote/Tar:

The Creosote Council II is disconcerted by the requirements of the Registration Standard for the chemical characterization of creosote and creosote/tar. It is the position of the Creosote Council II that the characterization of nonsynthetic complex mixtures like creosote should be "resolved by reliance on physical properties.... It is the most, direct, efficient, and reliable way to characterize creosote.... Efforts to characterize creosote products for any purpose by means other than physical properties, specifically AWPI specified methods, are without use and the cost of which should not be borne by the industry."

DEB disagrees with this position. It is feasible and common to characterize complex mixtures in chemical terms. For example, wine, beer, and whiskey are complex mixtures yet are readily characterized as alcoholic beverages containing a measurable

percentage of ethanol.

The product chemistry requirements of 40 CFR 158.120 as cited in Tables A and B ask that the creosote composite test materials (Table A) and the creosotes of the individual registrants (Table B) be analyzed for major constituents, that the results be reported in the form of a Confidential Statement of Formula, that 5 or more batches be analyzed and that the analytical methods be fully described and validated. We can see nothing onerous and incapable of accomplishment in asking the creosote industry to meet these product chemistry requirements of the Data Call-In.

In a previous submission of the Creosote Council (June 11, 1987), the individual members of the Council provided such analyses of their creosote products.

The methodology is available (see appendix to Creosote Council II's present submission).

We agree with the Creosote Council II's position that, in some instances, it is difficult to attribute the biological effects of complex mixtures to individual components of the mixtures. One component may be the active ingredient or several components may be acting in concert or antagonistically to produce the observed effect. However, the difficulty of ascribing biological effects of creosotes and coal tar to specific chemical entities does not absolve the registrants from the requirement of providing product chemistry data.

Request for Waiver of Product Chemistry Parts 61-1 and 61-2 of 158.120 of Table B of Registration Standard:

Table B as given in the Registration Standard Guidance Document seeks identification of components in individual producers' registered creosote products as distinct from the industry wide composite test material treated in Table A. Table B is in error in requiring the data be generated from "distillate fractions" or "distillate ranges". The data should be obtained from the individual producers' creosote products corresponding to the test materials of Table A. Similar data and the methodology for obtaining it is already in hand (see discussion above).

DEB recommends that the creosote industry be absolved from providing the data for distillate fractions of creosote products. However, the individual registrants must provide all of the requested product chemistry information for their individual creosote products in a manner similar to that required of the industry-wide composite test materials.

cc: Creosote Registration Standard, R.F., S.F., Circ., Reviewer, PMSD/ISB

RDI:PE:9/22/88:RDS:9/22/88
TS-769:JG:jg:803a:557-1439:9/22/88

U.S. ENVIRONMENTAL PROTECTION AGENCY
 Washington, D.C. 20460
 Registration Phase 2 Response Worksheet

PART B
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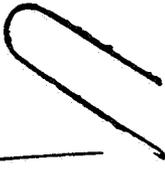
1. Company Name _____ 2. Case Name Coal Tar Creosote

3. Chemical Name _____ 4. Chemical Number _____

DTM for PI

Case Number	# STUDIES RECEIVED	# STUDIES RECEIVED	STUDIES REVIEWED	STUDIES NOT REVIEWED	REQUIREMENT FULFILLED	REQUIREMENT OUTSTANDING
63-12	REQUIRED	RECEIVED	RECEIVED	RECEIVED		
63-13	NO					
63-14						
63-15						
63-16						
63-17						
63-18						
63-19						
63-20						
63-21						
71-1	NO					
71-2(a)	NO					
71-2(b)	NO					
71-3	NO					
71-4(a)	NO					
71-4(b)	NO					

NOTES





U.S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460
Registration Phase 2 Response Worksheet

PART D

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1. Company Name: CTM for PI
 2. Case Number: _____
 3. Case Name: Coal Tar / Cresosote
 4. Chemical Name: _____

Case Number	Case Name	Chemical Name	RECEIVED	# STUDIES RECEIVED	STUDIES REVIEWED	STUDIES NOT REVIEWED	REQUIREMENT FULFILLED	REQUIREMENT OUTSTANDING
71-3(a)	Simulated field study		REQUIRED					
71-3(b)	Actual field study		NO					
72-1(a)	Fish toxicity bluegill		YES					
72-1(b)	Fish toxicity bluegill - TEP		YES					
72-1(c)	Fish toxicity rainbow trout		YES					
72-1(d)	Fish toxicity rainbow trout - TEP		YES					
72-2(a)	Invertebrate toxicity		NO					
72-2(b)	Invertebrate toxicity - TEP		NO					
72-3(a)	Estu/marl tox. fish		YES					
72-3(b)	Estu/marl tox. mollusk		NO					
72-3(c)	Estu/marl tox. shrimp		YES					
72-3(d)	Estu/marl tox. fish - TEP							
72-3(e)	Estu/marl tox. mollusk - TEP							
72-3(f)	Estu/marl tox. shrimp - TEP							
72-4(a)	Early life stage fish		YES	*				
72-4(b)	Life cycle invertebrate		YES	*				

NOTES * Fresh water species must be tested
 * COMPOSITE W/ P13
 as required by the NEW AGREEMENT 10/18/89

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Washington, D.C. 20460
Reregistration Phase 2 Response Worksheet

PART B

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1. Company Name: LT17 for 13

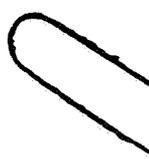
2. Chemical Name: Coar/Tar/Creosote

3. Case Number: _____

4. Chemical Number: _____

Condition Reference Number	Title of Study	REQUIRED	RECEIVED	# STUDIES RECEIVED	STUDIES REVIEWED	STUDIES NOT REVIEWED	REQUIREMENT FULFILLED	REQUIREMENT OUTSTANDING
63-12	Flammability	YES						
63-13	Stability	NO						
63-14	Oxidizing/Reducing Action							
63-15	Toxicity							
63-16	Explosibility							
63-17	Thermal stability							
63-18	Viscosity							
63-19	Miscibility							
63-20	Corrosion characteristics							
63-21	Ultimate breakdown vol%							
71-1	Acute avian oral quail/duck	NO						
71-2(a)	Acute avian diet quail							
71-2(b)	Acute avian diet duck							
71-3	Wild mammal toxicity							
71-4(a)	Avian repro. quail							
71-4(b)	Avian repro. duck							

NOTES





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Washington, D.C. 20460
Registration Phase 2 Response Worksheet

PART D

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1. Company Name	2. Case Number
3. Chemical Name	4. Case Name
5. Chemical Number	

CTM for P13

Coal Tar / Creosote

Guideline Reference Number	Title of Study	REQUIRED	RECEIVED	# STUDIES RECEIVED	STUDIES REVIEWED	STUDIES NOT REVIEWED	REQUIREMENT FULFILLED	REQUIREMENT OUTSTANDING
71-3(a)	Simulated field study	NO						
71-3(b)	Actual field study	NO						
71-3(a)	Fish toxicity bluegill - TEP	NO						
71-3(b)	Fish toxicity bluegill - TEP	NO						
71-3(c)	Fish toxicity rainbow trout	NO						
71-3(d)	Fish toxicity rainbow trout - TEP	NO						
71-3(e)	Invertebrate toxicity	NO						
71-3(f)	Invertebrate toxicity - TEP	NO						
71-3(a)	Estu/marl box fish	YES						
71-3(b)	Estu/marl box mudlark	YES						
71-3(c)	Estu/marl box shiner	YES						
71-3(d)	Estu/marl box fish - TEP	YES						
71-3(e)	Estu/marl box mudlark - TEP	YES						
71-3(f)	Estu/marl box shiner - TEP	YES						
71-4(a)	Early life stage fish		YES					
71-4(b)	Life cycle invertebrates		YES					

ESTUARINE SPECIES
to be tested

NOTES
Composite with P1
as required by the NEW AGREEMENT 10/18/89