

Shaughnessy No.: 22003
Date Out of EAB: NOV 7 1988

To: Lois Rossi/Sidney Jackson
Product Manager Team 21
Registration Division

From: Paul Mastradone, Acting Chief *PM*
Environmental Chemistry Review Section #1
Environmental Fate and Ground-Water Branch (TS-769C)

Through: Henry Jacoby, Acting Chief *Henry Jacoby*
Environmental Fate and Ground-Water Branch (TS-769C)
Environmental Fate and Effects Division

Attached, please find the EAB review of . . .

Reg./File # : 61-94
Chemical Name : Creosote
Type Product : Wood Preservative
Product Name : -
Company Name : Kopper/Creosote Council
Purpose : Response to Registration Standard

Date Received: 8-24-88 Action Code: 650

Date Completed:  NOV 7 1988 EAB # (s): 80973

Monitoring Study Requested: Total Reviewing time: 8 hours

Monitoring Study Volunteered:

Deferrals to: Ecological Effects Branch
 Residue Chemistry Branch
 Toxicology Branch

1. CHEMICAL: Common name: Creosote

Chemical name: Creosote

Structure: N/A

2. TEST MATERIAL: N/A

3. STUDY/ACTION TYPE: Response to Registration Standard

4. STUDY IDENTIFICATION: None

5. REVIEWED BY:

Paul J. Mastradone
Acting Section Chief
Review Section #1
OPP/EFGWB/EFED

Signature

Paul J. Mastradone

Date

NOV 7 1988

6. APPROVED BY:
Henry Jacoby, Acting Chief
OPP/EFGWB/EFED

Signature

Henry Jacoby
11/8/88

Date

7. CONCLUSIONS:

1. EFGWB recognizes the inherent problems in testing mixtures or parts of mixtures. This is one of the reasons that environmental fate data was reserved pending the submission and review of product chemistry data. EFGWB also recognizes some of the shortcomings of selecting marker or representative compounds to reflect the fate of all or part of the mixture.

8. RECOMMENDATIONS:

EFGWB suggests that the AWPB proceed with the product chemistry requested. Upon receipt and review of the requested product chemistry EFGWB will suggest, what if any data requirements should be required; what the test substance should be and suggested time for completion. At that time AWPB may wish to request waivers of the required data citing all appropriate data. Specific sections of the document noted in this letter and other literature pertains to specific studies should be cited in support of the waiver requests. In addition EFGWB suggests that a copy of the report Complex Mixtures Methods For In Vivo Testing (National Academy Press 1988) for review by appropriate EFED personnel.

9. BACKGROUND:

Response to Registration Standard of July 12, 1988.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

N/A

11. COMPLETION OF ONE-LINER:

N/A No data at this time.

12. CBI APPENDIX:

N/A

KOPPERS

John H. Butala
Toxicologist and Manager
Occupational Health and Product Safety

July 8, 1988

Lois Rossi
Product Manager 21
Registration Division (TS-767C)
Office of Pesticide Programs
U.S. E.P.A.
401 M Street, S.W.
Washington, D. C. 20460

Re: Creosote/Coal Tar Registration
Standard

Dear Ms. Rossi:

This communication is submitted to EPA in response to the April, 1988 Registration Standard and Data Call-In Notice for Pesticide Products Containing Coal Tar/Creosote as the Active Ingredient to be captioned Registration Standard on behalf of the companies indicated in J. Conner's letter of July 12, 1988.

For purposes of clarity, it is the objective of the industry to maintain pesticide registrations for two creosote products: P1/P-13, a coal tar creosote for land, fresh water, and marine (coastal) wood preservation use and P-2, a creosote-coal tar solution. Accordingly, we anticipate that other current registrations will be voluntarily cancelled and two composite creosote samples will be prepared for testing.

With regard to the language and requirements of the Registration Standard, it is the position of the Council that a number of points in that Standard and accompanying documents are in error. The Council would like to take this opportunity to address these issues. The first is the description of the substances covered by the Standard. Within the text of the Standard the Agency has employed four approaches to describing creosote or creosote products. Simultaneously, the Agency expresses awareness of the variable composition of creosote as a characteristic of an entity that is a nonsynthetic complex mixture. Examples of other complex mixtures considered as entities are not new to the Agency. Volume V of the 1985 TSCA Inventory is given over entirely to mixtures with unknown or variable composition and, as with creosote, CAS Registry Numbers have been assigned to the approximately 21000 entries. In the practical sense, issues of characterization of widely used materials like creosote have been resolved by reliance on physical properties. This is the course employed by the AWPI and one method acknowledged by EPA in the Standard. It is the most direct, efficient, and reliable way to

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characterize creosote. Clearly, one objective of the requirements of this standard is to develop a better understanding of the influence of compositional factors on biological activity. Historically a number of attempts have been made in varying depths of analyses to address such a question for other mixtures. The petroleum industry has been pursuing this question (about petroleum-derived mixtures) since the mid-1940's and on a broader scale the Health Effects Research Laboratory of the EPA has been active at least since the mid-1970's. Overall, the work of assessing the contribution of components to the toxicity of a mixture like creosote has not yet been completed by anyone attempting the project. It is the position of this Council then, that 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.

The second point this Council wishes to address is the use pattern of creosote. As a result of the negotiated settlement of the RPAR directed at creosote, that product, now a restricted use pesticide, is registered and labeled as a domestic outdoor use pesticide. By Agency declaration, uses of creosote not included in 40 CFR 158 Appendix A Domestic Outdoor Use Pattern are prohibited.

The final point this Council wishes to bring to your attention to is the inappropriate comparison between exposure to coke oven emissions and exposure to creosote. The comparison was drawn ostensibly to support an argument for oncogenicity and epidemiology studies on creosote because both coke and creosote derive from coal. Without detailing the substantial qualitative and quantitative differences between these industrial processes, it is most illustrative to appreciate that even within a coke oven battery only topside workers were found to be at excessive risk of developing occupationally induced cancer (IARC Vol. 34). The similarities of exposures among coke oven workers exceeds those between wood preservers and coke oven workers.

On behalf of its membership, the Creosote Council II requests a waiver of the following testing requirements:

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1. Table B Part 158-120 Product Chemistry Parts 61-1 and 61-2

These portions of the testing requirements seek identification of distillate fractions in creosote. By virtue of the arguments presented above and the lack of distinction between the terminology "distillate range" and "distillate fraction", the Council seeks relief from these requirements.

2. Table A Part 158.130 Environmental Fate

Although the Agency has stipulated that selection of environmental fate testing procedures and test materials be reserved until completion of Agency evaluation of product chemistry and other data, it is the opinion of the Council that adequate methods do not exist for environmental fate assessment of complex mixtures. Current methodologies for such assessment rely on the use of radiolabeled isotopes of test chemicals for environmental tracking. By definition this is not possible for a complex mixture. There is no validated method for tracking or otherwise characterizing the environmental fate of mixtures. A pertinent account of this dilemma is presented in the recent National Research Council report from the Board on Environmental Studies and Toxicology. The report is entitled, Complex Mixtures - Methods for In Vivo Testing (National Academy Press, 1988). In that report the Methods Committee writes that it is, "impractical or impossible to measure the concentrations of all the constituents of a complex environmental mixture in an exposure environment." (p. 13). The Committee recognizes that indicator molecules have been used to assess mixtures based on the assumption that the behavior of a constituent of the mixture is representative of the mixture. In judging this approach, the Committee cites the example of benzo(a)pyrene, or BaP, a carcinogenic polynuclear hydrocarbon. Essentially the Committee cites research from six independent sources which collectively indicated that the BaP content of two complex mixtures, cigarette smoke and coal tar pitch volatiles, failed to correlate with end points associated with the mixture. The Committee concluded that, "BaP at best is a crude indicator of the carcinogenic potential of a complex mixture. This example is pertinent because it suggests that additional compounds in a complex mixture can be important in the expression of the response and that the physical phase of the indicator can play a role." The report also mentions EPA use of other indicators for complex mixtures. The concluding statement in this section of the report

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is, "In the Committee's judgment, the validity of these indicator chemicals as hazard indices varies from very good (for ozone in air pollution) to very questionable (for particulate matter)."

These statements were made following a study of air pollution data. Although the physical matrix differs, the Creosote Council believes that what the National Research Council has learned about complex mixtures can be applied to creosote and urges you to consider the experience of the NRC's Board of Environmental Studies in regard to the state-of-the-art assessment of complex mixtures. In doing so we ask that you give appropriate weight to the NRC's conclusions on the use of surrogate substances for mixtures and also on the absence of any validated alternative methodology.

3. Table A Part 158.35 Dermal Exposure Assessment of Worker Exposure

Fixed station air monitoring (area sampling) and personal air monitoring procedures for workplace exposure assessment are well known to the membership of the Council. Protocols for this work that are in accord with standard industrial hygiene practices as defined by the American Board of Industrial Hygiene will be submitted under separate cover for Agency review. However, this Council is unaware of any reliable method for quantitative assessment of dermal exposure to an environmental chemical contaminant. There are reports of exposure badge and skin wipe tests that have been employed experimentally in an attempt to address this question. In no case that we are aware of has a dermal exposure measurement technique been endorsed by any scientific or regulatory body. Therefore, in the absence of a demonstrated, acceptable method for data production, we ask to be excused from this testing requirement.

4. Table A Part 158.35 Epidemiology Questionnaire and Feasibility Study

The Creosote Council supports development and maintenance of woodpreserving industry worker epidemiological data. Contrary to the statements appearing on page 2 of the EPA Pesticide Fact Sheet for Coal Tar/Creosote, epidemiology studies of the workers using coal tar creosote in a woodpreserving plant do exist. Copies of the reports of those studies are appended herein. Accordingly, the Council requests a waiver from the EPA for the requirements to perform an epidemiology feasibility study and for execution of the accompanying questionnaires. Further to the point, it should be noted that no member of the Council owns or operates a saw mill. Hence, the feasibility study as conceived by the EPA is compromised failing inclusion of a proper control group.

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As an alternative consideration, the Council proposes that existing epidemiology studies be supported with a validation effort to consist of a formal assessment and statement of the adequacy of the existing studies protocol, fidelity of the conduct of the studies and extent of employee participation in the studies.

5. Table A Part 158.135 Sections 81-1, 81-2, 81-4, 81-5, 84-2
84.4

The requirements in these sections are for acute mammalian and genetic toxicity testing of creosote samples. Submitted along with this correspondence are reports of acute mammalian and genetic toxicity studies conducted on creosote.

All of the studies reported were conducted some time ago well in advance of the publication of EPA Testing Guidelines and Good Laboratory Practice Regulations. The mammalian work was conducted at a prominent laboratory which continues to conduct investigations today. The identity and characterization of the creosote test sample are known, documented, and appended to this letter. Upon inspection you will find that the make-up of the creosote test sample used in 1964 matches PI/P13 specifications and fall within ranges stipulated as representative by the registrants. We believe that this presents strong justification for our claim to producing a consistent, standard product and to the relevance of these product standards set forth in our earlier presentations.

It is our contention that blends of creosote would produce acute toxic reactions in rodents that are indistinguishable from those exhibited by the sample tested. Laboratory observations issuing from the completed study are consistent with nonspecific irritation and digestion organ architectural damage. The Council asserts that other creosote samples will not result in biologically significantly different changes in test animals. Because of this, the Council is not anticipating label changes insofar as signal word, warning and precautionary statements, or first aid.

The Council believes that poor resolution and imprecision in acute mammalian toxicity testing indicate against additional short-term testing of creosote. Outside of the context of a business interest, the Council is committed to a more general progressive approach to product safety evaluation. Where it is responsible to do so, the Council seeks alternatives to animal testing for toxic effects. One element of this approach is the

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careful and judicious employment of animals in safety testing. In following selective application of animals in routine testing the Council believes that it is using a plan that the EPA will ultimately follow. In September of last year, EPA Assistant Administrator John Moore initiated a review within the Agency Science Advisory Panel of requirements for health and safety testing of pesticides. Specifically mentioned by Dr. Moore for reevaluation was the rationale to continue to require the number and extent of acute mammalian toxicity tests for registration. At the Council we believe that additional acute toxicological testing of creosote in light of the data available would be a senseless waste of animals and is exactly the kind of testing requirement Dr. Moore has summoned for review.

6. Table A Part 158.145

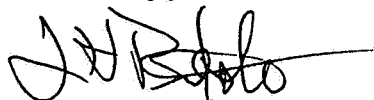
Sections of Part 158.145, Wildlife and Aquatic Toxicity Testing, have been written for testing of treated wood. The Council does not believe that under FIFRA the Agency has the authority to require testing of treated wood.

7. Table A Part 158.145 Sections 72-1, 72-2, 72-3, 72-4, 72-5, 72-6, 72-7, and 72-8

As per the arguments provided above, the sole use pattern for creosote is Domestic Outdoor. All of the testing required in the above sections is based on an Aquatic Non-food use pattern. Therefore, the Council asks to be excused from these testing requirements.

Finally, the Creosote Council II requests an extension of one year for submission of 90-day inhalation toxicity data and two years for teratology data. The reason for requesting the extension in the case of the inhalation study is to allow for adequate development and validation of real-time methods for vapor phase analysis of creosote necessary to monitor inhalation chamber concentrations (dose). In the case of teratogenicity work, the laboratory with the best reputation for quality performance of teratological studies is, in this case, also the laboratory with the most significant relevant testing experience, e.g., TSCA Section 4 testing of creosols. This laboratory cannot schedule creosote teratogenicity until July, 1989.

Sincerely,



John H. Butala, D.A.B.T.
Chairman, Creosote Council II
Technical Panel

Att.