

INFORMATION CONTACT:

Mr. Clinton B. Spotts, Regional EIS Coordinator, US Environmental Protection Agency, Region 6, 1201 Elm Street, Dallas, Texas 75270 (Telephone: (214) 767-2716 or (FIS) 729-2716).

SUMMARY: Pursuant to EPA regulations for new source NPDES permits and the preparation of EIS's (40 CFR Part 6), EPA is preparing a Draft EIS for wastewater discharges from the proposed Martin Lake Mining Area D lignite surface mine located in Rusk County, northeast of Henderson, Texas and proposed by Texas Utilities Generating Company. A detailed Notice of Intent that describes the project and identifies potential environmental impacts can be obtained from the person identified above. EPA will hold a meeting to determine the scope of the Draft EIS on January 28, 1982, at 7:30 pm at the County Courthouse, Rusk County Courthouse, 115 N. Main, Henderson, Texas.

Dated: January 5, 1982.

Paul C. Cahill,

Director, Office of Federal Activities.

[FR Doc. 82-545 Filed 1-7-82; 8:45 am]

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[OPTS 42004; TSH-FRL-1988-7]**Chlorinated Paraffins; Response to the Interagency Testing Committee**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the initial report of the Interagency Testing Committee (ITC), transmitted to the EPA on October 4, 1977, the Committee recommended to the Administrator of the EPA the chemical category "chlorinated paraffins" for consideration for testing. Earlier that year, an international group of chlorinated paraffin manufacturers had formed a Consortium to test their products for both health and environmental effects. The EPA has discussed the planned testing with the Consortium and finds the proposal from the Consortium to test chlorinated paraffins voluntarily for their health and environmental effects to be acceptable. Consequently, the EPA is not at this time proposing a section 4(a) rule to require health or environmental effects testing of the chlorinated paraffins.

FOR FURTHER INFORMATION CONTACT:

John B. Ritch, Jr., Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460, toll free (800-424-9065); in Washington, D.C. (554-

1404); outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:**I. Background**

Section 4(a) of the Toxic Substances Control Act (TSCA) authorizes the Administrator of the EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemicals may present to health and the environment.

Section 4(e) of TSCA (section 4(a); 90 Stat. 2003; (15 U.S.C. 2601 et seq.)) established an Interagency Testing Committee (ITC) to recommend to the EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC may designate up to 50 of its recommendations for priority consideration by the EPA. TSCA requires the EPA to respond to such designations within 12 months of the date they are made, either by initiating rulemaking under section 4(a) or publishing in the Federal Register reasons for not initiating rulemaking.

The ITC placed chlorinated paraffins on its priority testing list in October 1977. The ITC recommended testing of chlorinated paraffins for carcinogenicity, mutagenicity, teratogenicity, and other chronic effects in mammals, and persistence, environmental fate and chronic effects on aquatic organisms.

The ITC defined the category as "a series of mixtures of chlorination products of materials known commercially as paraffin oils or paraffin waxes; those having a chlorine content of 35 percent through 64 percent by weight are included." The EPA has expanded the category by increasing maximal chlorine content to 70 percent by weight, the highest possible. In addition, the Agency has excluded from consideration all such products that might have the same basic structure as a

chlorinated paraffin, but were produced in a different manner, e.g., polyvinyl chloride.

II. Proposed Testing

In 1977, an international group of chlorinated paraffins manufacturers had formed a Consortium to test their products for health and environmental effects. In response to the ITC notice, this Consortium of chlorinated paraffin manufacturers sent information to the EPA on their testing scheme. This section describes the final testing proposed by the Consortium, which reflects discussions of the Consortium with the EPA since 1979.

A. Compounds To Be Tested

There are various ways in which chlorinated paraffins might be grouped for purposes of determining which substances should be tested. The Chlorinated Paraffins Consortium, concluding that "99 percent of all chlorinated paraffins sold fell within the range C₁₀-C₃₀, Cl 40-70 percent by weight," classified chlorinated paraffins according to carbon chain length and percent chlorination as shown in Figure 1. The compounds named in the figure are those chosen for the Consortium testing program, and were selected as representative of the various structure types—long chain, short chain, medium chlorination, etc. While this scheme does not provide testing of all possible "chlorinate paraffins," the EPA believes that a chemical structure-based approach, such as this, should provide the necessary data base for chlorinated paraffins. The four representative compounds are chosen from the matrix categories that the Agency believes to be of major commercial significance. Industry representatives have stated at the public meeting described in unit III of this notice that the "empty" matrix boxes of Figure 1 represent substances of little or no domestic commercial importance.

FIGURE 1.—PERCENT CHLORINATION BY WEIGHT

	40 to 50 pct Cl	50 to 60 pct Cl	60 to 70 pct Cl
Carbon chain length:			
C ₁₀ -C ₁₅	Chlorowax 40® 2 (liquid)		Electroline 570® (solid)
C ₁₆ -C ₂₀		Cereclor 552® (liquid)	
C ₂₁ -C ₃₀			Chlorowax 500C® (liquid)

B. Testing To Be Performed

The Consortium's present proposals are presented in table 1. Dialogue between the EPA and the Consortium has resulted in alterations to the original proposals, and the present protocols and types of tests reflect the result of those

discussions. During this period, Chlorowax 40® and Chlorowax 500C® were selected for inclusion in the National Toxicology Program (NTP) bioassay program.

Both the mammalian testing system and the aquatic system proposed by the Consortium are tiered testing systems. A

number of tests will be performed on all four of the test compounds. Additional testing will be done on the most toxic compound, as selected by the Consortium on the basis of the initial phase of testing. A complete listing is given in Table 1.

In addition, the American members of the Consortium have agreed to fund a one-compound chronic reproductive study on an avian species. The

compound to be tested has not yet been chosen.

The Consortium has agreed to permit Good Laboratory Practices/Quality Assurance (GLP/QA) activities at the request of authorized representatives of the EPA in connection with any and all studies being conducted by and for the Consortium. The Consortium has provided the EPA with protocols and will supply the EPA with the data from

the studies as soon as possible. Testing is expected to be completed by December 1983 and all the results will be made available to the public as soon as they are received by the EPA. In addition, the Consortium has agreed that Agency representatives may take part in discussions of interim test results, although final testing decisions will be made by the Consortium.

TABLE 1

	Chlorowax 500C®	Chlorowax 40®	Cereclor S52®	Electrofine S70®
MAMMALIAN HEALTH				
Phase 1:				
Tissue level and decay studies after single dose (rat)	X*	X	X	X
90-day oral subchronic toxicity* and metabolism studies	X	X	X	X
Cell transformation (styles) test	X			X
Dominant lethal mutation test (rat)*	X			X
<i>In vivo</i> cytogenetic test (rat)	X	X	X	X
Teratology (rat, rabbit)	X	X	X	X
Phase 2 (1 compound, most toxic in phase 1): 2 generation reproduction study (rat).				
ENVIRONMENTAL				
Phase 1: 30-60 day lethal and sublethal (mussel, rainbow trout)	X	X	X	X
Phase 2 (Chlorowax 500C®R, already known to be most toxic from phase 1 aquatic studies):				
Growth (rainbow trout, mussel)				
Bioconcentration (rainbow trout, mussel)				
Life cycle (<i>Daphnia</i> , mysid shrimp)				
Embryo-juvenile (sheepshead minnow)				
14-day bioassay (freshwater alga, marine alga)				
Chronic (partial life-cycle) (midge)				
Sediment				
Biodegradation (aerobic, anaerobic)				
Avian Study (test substances to be selected)				
Reproductive study (duck)				

*X=Study being performed by Consortium.

*The Agency considers that 90-day subchronic toxicity tests are acceptable in most cases as predictive of chronic effects.

*Because NTP is doing full scale 2-year bioassays on Chlorowax 500C® and Chlorowax 40® the EPA did not feel it was necessary to do cell transformation tests for these substances.

The cell transformation tests for Chlorowax 500C® and Electrofine S70® are being done for the Consortium's purpose.

*Information is already available on dominant lethal mutation tests for Chlorowax 40® and Chlorowax 70® (an analogue of Electrofine S70).

*This study is not part of the proposal by the international Chlorinated Paraffins Manufacturers Consortium, and will be performed by the American members.

III. Public Meeting on Proposed Industry Program

A public meeting was held on September 15, 1981 (notice was given in the Federal Register of August 27, 1981, 46 FR 43298), to allow interested persons to comment on the industry testing program as an alternative to the promulgation of a test rule at this time.

On October 21, 1981, the EPA received and has subsequently reviewed comments from the Natural Resources Defense Council (NRDC) on the proposed voluntary testing scheme. NRDC appears to believe that by agreeing to the voluntary testing scheme the Agency has forfeited the right to propose and/or require additional testing of chlorinated paraffins in the future. The EPA explicitly retains this right and has decided not to propose testing at this time because the Consortium program will provide considerable data, and even if some aspect of the testing later proves insufficient, EPA will be in a better position to evaluate additional testing needs when the voluntary testing

program is completed (see unit IV, following).

The following discussion relates to NRDC's specific comments on the chlorinated paraffins testing scheme. A brief exposition of the EPA's general legal position appears in the alkyl phthalate notice published elsewhere in this issue of the Federal Register. A more detailed discussion of these issues and a discussion of NRDC's general comments on voluntary testing programs are provided in memoranda on the public record of this proceeding.

Several of NRDC's comments discussed the failure of the Consortium's testing program to contain certain types of testing included in the proposed Test Rule for Dichloromethane and 1,1,1-Trichloroethane published in the Federal Register of June 5, 1981 (46 FR 30300). However, each chemical has different characteristics and different combinations of risk factors, and the types of testing appropriate for one may not be chemically appropriate for all chemicals. It is the EPA's belief that the chlorinated paraffins as a class are unlikely to pose the types of potential

hazards that the solvents dichloromethane or 1,1,1-trichloroethane might. For example, the chlorinated paraffins have very low acute toxicities, with some LD₅₀s exceeding the 10 g/kg level. They are non-volatile, have a low chemical reactivity, and are not closely related to known oncogens or mutagens. Mutagenicity studies have been negative, and while toxic effects have been seen in the dog and rat these have been in the liver and kidney, with no reported effects in the reproductive organs to indicate an unreasonable risk of reproductive effects.

The EPA is not proposing terrestrial plant testing or a terrestrial bird reproductive study because the Agency believes it can reasonably predict that chlorinated paraffins will not pose an unreasonable risk to terrestrial ecosystems. Available evidence indicates that they are not found in such ecosystems to any great extent, whereas chlorinated paraffins have been measured in water, sediment, fish, aquatic mammals, and in seabirds and their eggs.

NRDC proposes that the EPA require, at a minimum, biodegradation studies and life cycle studies in *Daphnia magna* and mysid shrimp on all chlorinated paraffins tested, to indicate the potential for chronic toxic effects at low levels. However, the Agency believes that biodegradation studies will not indicate the potential for chronic toxic effects at low levels. In addition, subchronic 30-60 day studies are already being done in an aquatic invertebrate, the mussel, which is a bottom feeder and would be expected, owing to the physical and chemical properties of this class of compounds to be exposed to higher levels of chlorinated paraffins in the environment than *Daphnia* or mysid shrimp, which live in the water column.

NRDC also suggested that the chlorinated paraffins to be tested should include representatives of the low chain length, low chlorination substances, or representatives of the boxes immediately adjacent to that one, i.e., medium chain length, low chlorination, and low chain length, medium chlorination (see Figure 1). The EPA has not proposed testing of compounds in these subcategories because the EPA has no information demonstrating that such compounds are either manufactured or available in the United States in any significant quantities.

The Consortium has submitted an approximate testing schedule to the Agency. Much of the testing has already been completed, and the remainder is expected to be finished by December 1983. If the EPA were to pursue issuance of a test rule on these chemicals, the rule would probably not be final before July 1983 and testing would not actually begin for several months after that. Therefore the Agency believes that the Consortium's scheme will produce results at least as fast and in most cases faster than would be obtainable under a test rule.

The final concern raised by NRDC relates to the Consortium's concept of selecting the compound found to be "most toxic" in Phase 1 studies for investigation in Phase 2. The EPA has not insisted that the Consortium provide detailed decision logic in advance of receipt of the test results because of the many possible combinations of data that may arise in Phase 1. The Agency is not bound to accept the Consortium's interpretation of the data, and as the EPA will have access to all the data generated, Agency scientists will be able to evaluate the information on which the Consortium based its decision. If the EPA does not agree with the Consortium's choice and feels that

additional testing needs to be done, the Agency can still require it.

In sum, the EPA has weighed the comments received and finds that it can accept the proposal as described in the preceding part of this notice.

IV. Decision Not To Require Testing

The EPA feels that the Chlorinated Paraffins Consortium's testing proposal, together with the NTP bioassays, will meet the immediate testing concerns of the Agency for the chlorinated paraffins. For this reason the EPA has decided not to require additional testing of the chlorinated paraffins at this time.

Acceptance of this voluntary testing proposal has great advantages over the full regulatory process. The Consortium has already completed many of the listed tests. Because the Phase 1 studies have already been completed, the evaluation of the category as a whole, and the Consortium has agreed to consider testing additional compounds in the Phase 2 tests if serious toxicities are shown to occur, the acceptance of the Consortium's proposal seems a reasonable alternative to a time-consuming and expensive formal rulemaking proceeding under TSCA section 4(a). This allows the Agency to focus upon other testing needs not covered by voluntary testing agreements. Considering the Agency's present test rules burden, and the considerable amount of testing included in this testing proposal, the EPA has determined that the public interest will best be served by the Consortium's and the EPA's mutual cooperation in this testing program. Should test results or other information reveal a need for additional testing that the Consortium is unwilling to perform, the Agency reserves its right to require testing under section 4(a).

V. Public Record

EPA has established a public record for this testing decision (docket number OPTS-42004) which is available for inspection from 8 a.m. to 4 p.m. Monday through Friday, except legal holidays, in Rm. E-107, 401 M St. SW., Washington, D.C. 20460. This record includes basic information considered by the Agency in developing this decision. The Agency will supplement the record with additional relevant information as it is received. The record includes the following information.

- (1) Federal Register notice containing the designation of chlorinated paraffins to the Priority List.
- (2) Communications before proposal:
 - (a) Letters.
 - (b) Contact reports of telephone conversations.

- (c) Meeting summaries of Agency-industry meetings.
- (d) Public comments.
- (e) Memorandum responding to public comments.
- (3) Published data and some 8(d) submissions.
- (4) Testing protocols.
- (5) Data from Consortium's testing.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: December 30, 1981.

John W. Hernandez, Jr.,

Administrator.

[FR Doc. 82-371 Filed 1-7-82; 8:45 am]

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[OPTS-51375; TSH-FRL-2023-7]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the Federal Register of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of four PMNs and provides a summary of each.

DATE: Written comments by: PMN 81-652, 81-656, 81-657 and 81-658—February 21, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS-51375]" and the specific PMN number should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, D.C. 20460 (202-382-3532).

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-216, 401 M St., SW., Washington, D.C. 20460 (202-426-2601).

SUPPLEMENTARY INFORMATION: The following are summaries of information provided by the manufacturer on the PMNs received by EPA:

PMN 81-652

Close of Review Period, March 23, 1982.