

ENVIRONMENTAL PROTECTION AGENCY

(OPTS-42042A; TSH-FRL 2595-3)

4-(1,1,3,3-Tetramethylbutyl)phenol Decision To Adopt Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Federal Register of November 15, 1983, EPA announced a preliminary decision not to initiate rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require aquatic toxicity testing of 4-(1,1,3,3-tetramethylbutyl)phenol (TMBP) (CAS No. 140-66-9), pending consideration of public comments, and to accept a testing proposal submitted to EPA by the Octylphenol Program Panel (the Panel). No public comments were received other than those of the Panel. The Agency finds no reason to alter its preliminary decision and is not proposing a section 4(a) rule to require environmental effects testing of TMBP at this time.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 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: EPA is accepting the aquatic toxicity testing agreement for TMBP proposed by the Octylphenol Program Panel.

I. Background

On November 3, 1982 (47 FR 54624), the Interagency Testing Committee (ITC) recommended that 4-(1,1,3,3-tetramethylbutyl)phenol (TMBP) be considered for short-term health effects testing, including mutagenicity, and for environmental effects testing including acute and chronic toxicity to fish and aquatic invertebrates, toxicity to plants, bioconcentration, and chemical fate. In the Federal Register of November 15, 1983 (48 FR 57971), the Agency announced a preliminary decision not to initiate a rulemaking proceeding under section 4(a) of the Toxic Substances Control Act (TSCA) to require aquatic

toxicity testing of TMBP. This decision was based on the Agency's tentative acceptance of a testing proposal submitted by the Octylphenol Program Panel. In that notice the Agency also announced that it was not requiring health effects, bioconcentration or chemical fate testing because adequate data had become available to the Agency to reasonably predict TMBP's fate and bioconcentration in the environment and health effects of concern to the ITC.

A draft of the Panel's testing proposal, which contained all the protocols and protocol amendments to be employed in testing TMBP, was included in the public record (docket number OPTS-42042). The Agency requested comments on its tentative decision not to require testing of TMBP based on the proposed testing scheme.

II. Summary of Planned Testing Program

In order to address the concerns explained in the ITC's Eleventh Report of November 1982, the Panel presented to EPA a proposal for testing TMBP for environmental effects. The Panel's proposal for TMBP includes the following environmental tests:

1. *Measurement of TMBP in water.* The analysis for concentrations of TMBP in water and its solubility will be performed. This study will provide the basis for the quantification of TMBP in the following acute toxicity test systems.

2. *Toxicity to freshwater animals.* Flow-through acute toxicity tests with fathead minnow, rainbow trout, and *Daphnia magna* will be performed. When results and conclusions of these studies are available, they will be submitted to the Agency. These results and conclusions will be reviewed by the Panel and EPA personnel. Following this review, a determination by EPA will be made whether further testing, such as subchronic and chronic studies, should be conducted. The acute toxicity studies are scheduled to begin by November, 1984, with the final report submitted by March, 1985.

3. *Toxicity to freshwater plants.* A static acute toxicity test with the green algae *Selenastrum capricornutum* will be performed. When results and conclusions of this study are available, they will be submitted to the Agency. These results and conclusions will be reviewed by the Panel and EPA personnel. Based on this review the Agency will determine whether further aquatic plant toxicity testing should be conducted. These studies are scheduled to begin by November, 1984, with the final report submitted by March, 1985.

III. GLP's and Other Provisions

The Panel will be conducting aquatic toxicity testing using laboratory protocols which have been amended by the Agency to comply with the TSCA guidelines for environmental effects testing. The Panel has furnished EPA with the name and address of the laboratory that will conduct these tests. The Panel has stated that it will adhere to the Good Laboratory Practice Standards issued by the U.S. Food and Drug Administration, as published in the Federal Register of December 22, 1978 (43 FR 69986). The Panel also has agreed to laboratory inspections and study audits in accordance with provisions outlined in TSCA section 11 at the request of authorized representatives of the EPA. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluation thereof, and that the studies are being conducted according to the Good Laboratory Practice Standards.

The Panel has further agreed that all raw data, documentations, records, protocols, specimens, and reports generated as a result of each study will be retained for at least 10 years from the date of publication of this notice by EPA and made available during an inspection or submitted to EPA if requested by EPA or its designated representatives. Program reviews will be conducted by EPA at appropriate intervals throughout the program to assess the need for additional testing of TMBP.

The Panel understands that the Agency plans to issue, in the Federal Register, a notice of the receipt of all test data submitted by industry under this test program. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, any data submitted will be made available by EPA for examination by any person.

Finally, the Panel understands that failure to conduct the testing according to the specified protocols or failure to follow Good Laboratory Practices may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to promulgate a test rule or otherwise require further testing.

IV. Public Comment on the Panel's Proposed Testing Program

The Agency has received no public comment on EPA's decision not to test TMBP, based on the proposed testing scheme, other than those submitted by

the Panel. In its comments, the Panel acknowledged its support for the testing program and clarified minor amendments to the proposal which were submitted to EPA prior to publication of the notice of the proposed agreement and contained in the public docket for that notice.

V. Decision To Adopt Negotiated Testing Program

The Agency believes that this testing program, including any follow-up testing determined necessary based on the initial test results, will provide sufficient data to reasonably determine or predict the environmental effects of TMBP. Therefore, EPA is adopting this negotiated testing program. Depending on the results of the preliminary data review in this agreement, the Agency may determine that additional environmental testing should be conducted. If the Agency determines that additional testing should be conducted after evaluating the data developed during the negotiated testing program, and if industry fails to promptly initiate such testing, EPA reserves the right to propose a test rule to obtain the additional test data.

VI. Public Record

EPA has established a public record for this decision not to pursue testing under section 4 (Docket number OPTS-42042). This record includes:

- (1) Federal Register notice designating TMBP to the priority list (47 FR 54626) and all comments on TMBP received in response thereto.
- (2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.
- (3) Testing proposals and protocols.
- (4) Published and unpublished data.
- (5) Federal Register notice requesting comment on the negotiated testing proposals and comments received in response thereto (48 FR 51971).

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday except legal holidays, in Room E-107, 401 M St. SW., Washington, DC 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2801))

Dated: July 13, 1984.

William D. Ruckelshaus,
Administrator.

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