40 CFR Part 799

[OPTS-42034C (FRL-2991-9)]

Ethyltoluenes, Trimethylbenzenes, and the C9 Aromatic Hydrocarbon Fraction; Proposed Test Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA has issued a final rule for the first phase of a two-phase test rule under section 4(a) of the Toxic Substances Control Act (TSCA) requiring that manufacturers and processors of the C9 aromatic hydrocarbon fraction (C9 fraction) obtained from the reforming of crude petroleum test the C9 fraction for neurotoxicity, mutagenicity, developmental toxicity, reproductive effects, and oncogenicity (unless certain mutagenicity test results are negative). The Agency is now proposing that the protocols submitted by the American Petroleum Institute (API), with minor additions as proposed by the Agency, be adopted as the test standards for the C9 fraction under this test rule. The Agency is also proposing schedules for the testing. This notice begins the second phase of the C9 fraction test rule.

DATE: Submit written comments on or before May 12, 1986.

ADDRESS: Submit written comments, identified by the document control number (OPT-42034C), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, DC 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St. SW., Washington, DC 20460. Toll free: (800-424-9065). In Washington, DC: (544-1404). Outside the U.S.A.: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 17, 1985 (50 FR 20662), EPA issued a final Phase I rule under section 4(a) of TSCA to require testing of the C9 aromatic hydrocarbon fraction obtained from the reforming of crude petroleum for specific health effects. The Agency is now proposing that the industry-submitted protocols and additions to it as proposed by the Agency be adopted as the test standards for the required testing. The Agency is also proposing schedules for the testing.

I. Background

The ITC designated ethyltoluenes (mixed isomers) and 1,2,4-trimethylbenzene for priority testing consideration in its Tenth Report, published in the **Federal Register** of May 25, 1982 (47 FR 22585), and recommended in its Eleventh Report, published in the **Federal Register** of December 3, 1982 (47 FR 54624), that the other trimethylbenzenes (1,2,3- and 1,3,5-isomers) be considered for testing. EPA issued a proposed phase I test rule in the **Federal Register** of May 23, 1983 (48 FR 23088) under 40 CFR 799.1625 *C9 aromatic hydrocarbon*, which would require that testing of the C9 aromatic hydrocarbon fraction containing *ortho-*, *meta-*, and *para*-isomers of ethyltoluene and the 1,2,3-, 1,3,5- and 1,2,4-isomers of trimethylbenzene be performed. EPA promulgated the final phase I rule requiring testing of the C9 fraction in the **Federal Register** of May 17, 1985 (50 FR 20662). Because of a rearrangement of Part 799, the final rule for the C9 fraction was recodified to § 799.2175. For a detailed discussion of EPA's findings and testing requirements for the C9 fraction, the reader should refer to the final phase I rule. In accordance with the Test Rule Development and Exemption Procedures for two-phase rulemaking in 40 CFR Part 790, persons subject to this rule were required to submit letters of intent to perform the testing or exemption applications. Those submitting letters of intent were required to submit proposed study plans and schedules for the testing required in the final phase I rule.

Only July 31 and August 30, 1985, the U.S. manufacturers and processors of the C9 fraction jointly notified EPA of their intent to sponsor through the American Petroleum Institute (API) the testing required in the phase I test rule (Refs. 1 and 2). API submitted proposed study plans on September 30, 1985 (Ref. 3) and revisions to the plan on January 10, 1986 (Ref. 4).

EPA is now proposing that the submitted protocols, including the minor additions as proposed by EPA, be adopted as the test standards for the required testing of the C9 fraction. The Agency is also proposing schedules which it believes are more reflective of the time necessary to complete the required testing than those proposed by API.

II. Proposed Test Standards

API has notified EPA on behalf of those API members who are subject to this rule that it intends to conduct the testing required in the final phase I rule for the C9 fraction in 40 CFR 799.2175. API has submitted proposed study plans for the required testing (Refs. 3 and 4). The proposed study plans contain the following tests: *In Vitro* Mammalian Cytogenetics Assay utilizing Chinese Hamster ovary cells; *Salmonella typhimurium* Reverse Mutation Assay; *In Vitro* Sister Chromatid Exchange Assay utilizing Chinese Hamster ovary cells; *In Vitro* Mammalian Cell Mutagenesis Assay utilizing Chinese Hamster ovary cells; *In Vivo* Mammalian Bone Marrow Cytogenetics Assay in rats; *In Vitro* Mammalian Cell Mutagenesis Assay utilizing mouse lymphoma L5178Y cells; Sex-Linked Recessive Lethal Test in *Drosophila melanogaster*; Dominant Lethal Assay in rats; Heritable Translocation Assay in mice; Mouse Visible Specific Locus Test; Inhalation Carcinogenesis Study in rats and mice; Developmental Toxicity Study

in rats and mice: Two Generation (One Litter) Inhalation Reproduction Study in rats: and Neurotoxicity Study in rats.

API has stated that these studies will be conducted in accordance with EPA TSCA Good Laboratory Practice Standards as set forth in 40 CFR Part 792.

The proposed study plans are available in the public docket for this action. The test plans submitted by API have been reviewed by the Agency and generally conform to the TSCA Health Effects Test Guidelines in 40 CFR Part 798 for the required studies. Where exceptions exist, EPA has proposed that certain additions be made to guarantee conformity with the guidelines. These additions are being proposed in order to ensure that the data resulting from the required testing of C9 fraction are reliable and adequate. The Agency is proposing that these study plans with the specific additions be adopted as the test standards for performing the required health effects testing of the C9 fraction required under 40 CFR 799.2175.

III. Reporting Requirements

The Agency is proposing specific schedules for completing studies and submitting final reports on the required testing for the C9 fraction. The Agency believes that the schedules proposed by API and included in its proposed study plan allow for an unreasonable amount of time to take place before initiating testing and reporting the final results for all of the required studies. The Agency believes API's testing schedule is unacceptable.

The Agency, therefore, is proposing specific reporting requirements for each of the proposed test standards as follows:

A final report for the reproductive study shall be submitted to the Agency within 29 months of the effective date of the final phase II rule. Interim progress reports shall be provided quarterly.

A final report for the developmental toxicity study shall be submitted within 12 months of the effective date of the final phase II rule. Interim progress shall be provided quarterly.

A final report for the neurotoxicity study shall be submitted within 15 months of the effective date of the final phase II rule. Interim progress reports shall be provided quarterly.

The mutagenicity studies shall be completed and the final results submitted to the Agency as follows:

First tier gene mutation and chromosomal aberration tests within 1 year of the effective date of the final phase II rule.

Second tier gene mutation and chromosomal aberration tests within 2 years of the effective date of the final phase II rule.

Third tier gene mutation tests within 4 years of the effective date of the final phase II rule. Interim quarterly progress reports shall be provided for all tests.

The oncogenicity test, to be conducted unless certain tier I or II mutagenicity tests are all negative (see 50 FR 20677), shall be completed and the final results submitted to the Agency within 53 months after submission of the final results of the first non-negative mutagenicity test. Interim progress reports shall be provided quarterly.

As required by TSCA section 4(d), the Agency plans to publish in the Federal Register a notice of the receipt of any test data submitted under this test rule within 15 days after receipt of the data. Except as otherwise provided in TSCA section 14, such data will be made available for examination by any person.

IV. Issues for Comment

The Agency invites comments on the proposed study plans submitted by API and the additions proposed by EPA; copies of these study plans are included in the public record for this action. EPA also invites public comment on the proposed schedules for the required testing.

V. Public Record

EPA has established a record for this rulemaking, (docket number OPTS-42034C). This record includes basic information considered by the Agency in developing this proposal and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received.

This record includes the following information:

A. *Supporting Documentation*

1. Final Phase I rule on C9 aromatic hydrocarbon fraction (50 FR 20662).
2. Written public comments and letters.
3. Contact reports of telephone conversations.

B. *References*

1. API. Letter from W.F. O'Keefe to TSCA Public Information Office. U.S. Environmental Protection Agency, Washington, DC. 20460. July 31, 1985.
2. API. Letter from W.F. O'Keefe to TSCA Public Information Office. U.S. Environmental Protection Agency, Washington, DC. 20460. August 30, 1985.
3. API. Proposed Study Plan Toxicity Testing of Ethyltoluenes, Trimethylbenzenes and the C9 Aromatic Hydrocarbon Fraction. September 30, 1985.
4. API. Letter from W.F. O'Keefe to TSCA Public Information Office. U.S. Environmental Protection Agency, Washington, DC. 20460. January 10, 1986.

The record is available for inspection from 8 a.m. to 4 p.m., Monday through Friday except legal holidays, in Rm. E-107, 401 M Street SW., Washington, DC 20460.

VI. Other Regulatory Requirements

A. *Executive Order 12291*

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirements of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The economic analysis of the testing of the C9 fraction is discussed in the Phase I test rule (50 FR 20662).

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments received from OMB are included in the public record for this rulemaking.

B. *Regulatory Flexibility Act*

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses for the following reasons:

1. There are not a significant number of small businesses manufacturing the C9 fraction.
2. Small processors will not perform testing themselves, or participate in the organization of the testing efforts.
3. Small processors will experience only very minor costs, if any, in securing exemption from testing requirements.
4. Small processors are unlikely to be affected by reimbursement requirements, and any testing costs passed on to small processors through price increases will be small.

C. *Paperwork Reduction Act*

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070-0033. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs: OMB: 726 Jackson Place, NW.: Washington, DC 20503 marked "Attention: Desk Officer for EPA." The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous substances, Chemicals, Reporting and recordkeeping requirements.

Dated: March 18, 1986.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

Therefore, is proposed that 40 CFR Part 799 be amended as follows:

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. By amending § 799.2175 by revising paragraphs (d)(1)(ii), (2)(ii), (3)(ii), (4)(ii), (5)(ii), and (6)(ii) and adding new paragraph (e), to read as follows:

§ 799.2175 C9 aromatic hydrocarbon fraction.

* * * * *

(d) * * *

(1) * * *

(ii) *Reporting requirements.* (A) The mutagenicity effects testing for chromosomal aberrations as contained in the first tier of testing which consists of an *in vitro* cytogenetics test and an *in vivo* cytogenetics test shall be completed and the final results submitted to the Agency within 12 months of the effective date of this final rule.

(B) The mutagenic effects testing for chromosomal aberrations as contained in the second tier of testing which consists of a dominant lethal assay shall be completed and the final results submitted to the Agency within 24 months of the effective date of this final rule.

(C) The mutagenic effects testing for chromosomal aberrations as contained in the third tier of testing which consists of a heritable translocation assay shall be completed and the final results submitted to the Agency within 48 months of the effective date of this final rule.

(D) Progress reports shall be submitted to the Agency for all chromosomal aberration studies quarterly beginning 90 days after the effective date of this final rule.

(2) * * *

(ii) *Reporting requirements.* (A) The mutagenic effects testing for gene mutations as contained in the first tier of testing which consists of a *Salmonella typhimurium* mammalian reverse mutation microsomal assay, a sister chromatid exchange (SCE) assay, and a gene mutation in mammalian cells in culture assay shall be completed and the final results submitted to the Agency within 12 months of the effective date of this final rule.

(B) The mutagenic effects testing for gene mutations as contained in the second tier of testing which consists of a second gene mutation in mammalian cells in culture assay and a *Drosophila* sex-linked recessive lethality test shall be completed and the final results submitted to the Agency within 24 months of the effective date of this final rule.

(C) The mutagenic effects testing for gene mutations as contained in the third tier of testing and which consists of a mouse specific locus assay shall be completed and the final results submitted to the Agency within 48 months of the effective date of this final test rule.

(D) Progress reports shall be submitted to the Agency for all gene mutation studies quarterly beginning 90 days after the effective date of this final test rule.

(3) * * *

(ii) *Reporting requirements.* (A) The oncogenicity testing shall be completed and the final results submitted to the Agency within 53 months after submission of the first non-negative test results in any of the following tests: *in vitro* cytogenetics, *in vivo* cytogenetics (if required), first gene mutation in cells in culture, second gene mutation in cells in culture (if required), and *Drosophila* sex-linked recessive lethality (if required).

(B) Progress reports shall be submitted to the Agency quarterly beginning 90 days after submission of the first non-negative mutagenicity test results for any of the studies indicated in paragraph (d)(3)(ii)(A) of this section.

(4) * * *

(ii) *Reporting requirements.* (A) The developmental toxicity testing shall be completed and the final results submitted to the Agency within 12 months of the effective date of this final rule.

(B) Progress reports shall be submitted to the Agency quarterly beginning 90 days after the effective date of this final rule.

(5) * * *

(ii) *Reporting requirements.* (A) The reproductive effects testing shall be completed and the final results submitted to the Agency within 29 months of the effective date of this final rule.

(B) Progress reports shall be submitted to the Agency quarterly beginning 90 days after the effective date of this final rule.

(6) * * *

(ii) *Reporting requirements.* (A) The neurotoxicity testing shall be completed and the final results submitted to the Agency within 15 months of the effective date of this final rule.

(B) Progress reports shall be submitted to the Agency quarterly beginning 90 days after the effective date of this final rule.

(e) *Test standards*—(1) *General.* The required testing specified in paragraph (d) of this section shall be conducted in accordance with the study plans for testing the C9 fraction developed by the American Petroleum Institute (API), 1220 L St., NW., Washington DC 20005, and submitted to the Agency on September 30, 1985, and the additional requirements specified in paragraph (e) of this section. Copies of the API study plans are located in the public record for this rule (docket no. OPTS-42034) and are available for inspection in EPA's OPTS Reading Rm., E-107, 401 M St., SW., Washington, DC 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

(2) *Mutagenic effects.* For each study specified in paragraphs (d)(1) and (2)(i) (A), (B), (C), (D), and (E), the following are required.

(A) The study shall be repeated if a single, statistically significant dose group is detected that did not produce a dose-response effect.

(B) In addition to the criteria for determining a positive result given in the study plans specified in paragraph (e)(1) of this section, the detection of a reproducible and statistically significant response for at least one of the test substance concentrations shall be interpreted as a positive result.

(ii) For the mouse heritable translocation assay specified in paragraph (d)(1)(i)(D) of this section, the following are required.

(A) If the laboratory's historical control base is inadequate, concurrent positive and negative controls shall be conducted.

(B) Control data shall be presented whether it is historical or concurrent, and it shall be identified as either the one or the other.

(3) *Oncogenicity*—(i) *Dose levels and dose selection.* The lowest dose shall not be lower than 10 percent of the high dose.

(ii) *Duration.* Each study shall last the full life span of each species.

(iii) *Histopathology.* Target organs (including lungs and respiratory tract) in all animals shall be subject to a histopathological examination.

(iv) *Individual animal data.* (A) Food and water consumption data shall be reported.

(B) Ophthalmological data shall be recorded when the examination is performed.

(4) *Developmental toxicity.* Dams shall be killed before parturition.

(5) *Test substance*—(i) *Identity and source.* The remaining components, which may be as high as 25 percent of the test mixture, shall be characterized.

(ii) *Stability under test and storage conditions.* The atmosphere being inhaled by the animals shall be characterized with regard to [illegible] concentration and identification of the components inhaled.

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