**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 799**

**[OPTS–42034; TSH–FRL 2346–5]**

## Ethyltoluenes, Trimethylbenzenes, and the $C_9$ Aromatic Hydrocarbon Fraction; Proposed Test Rule

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** In its Tenth Report, the Interagency Testing Committee (ITC) designated mixed ethyltoluenes (ET) and 1,2,4-trimethylbenzene (1,2,4-TMB) for priority consideration for environmental and health effects testing. In its Eleventh Report, the ITC recommended that the other trimethylbenzenes be considered for testing. Under section 4(a) of the Toxic Substances Control Act (TSCA), EPA is proposing that manufacturers and processors of the $C_9$ aromatic hydrocarbon fraction, which contains ethyltoluene (*ortho-, meta-* and *para-*isomers), and the 1,2,3-, 1,3,5- and 1,2,4-isomers of trimethylbenzene as primary components, test the $C_9$ aromatic fraction for health effects, including neurotoxicity, mutagenicity, teratogenicity, reproductive effects and carcinogenicity (in the event the results of the mutagenicity studies are positive). Health effects testing would be performed according to test standards prescribed in a subsequent rulemaking. Environmental effects testing is not being proposed at this time. This notice constitutes EPA's response to the ITC's designation of ET (mixed isomers) and 1,2,4-TMB as priority candidates for testing, and to the ITC's recommendation that the other trimethylbenzenes (1,2,3- and 1,3,5-isomers) be considered for testing.

**DATES:** The public is asked to submit written comments on or before July 22, 1983. If persons request time for oral comment by July 7, 1983, EPA will hold a public meeting on August 8, 1983 on this rule in Washington, D.C. For further information on arranging to speak at the meeting see Unit VII of this preamble.

**ADDRESS:** Address written comments identified by the document control number (OPTS–42034) 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, D.C. 20460.

The administrative record supporting this action is available for public inspection at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

For exact time and place of meeting contact Jack P. McCarthy (see **"FOR FURTHER INFORMATION CONTACT"**).

**FOR FURTHER INFORMATION CONTACT:** Jack P. McCarthy, Director, Industry Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–511, 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. Introduction

Section 4(e) of TSCA (Pub. L. 94–469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated ET (mixed isomers) and 1,2,4-TMB for priority 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. These actions were based on the exposure potential and the lack of sufficient information on health and environmental effects.

Under section 4(a)(1) of TSCA, the Administrator shall by rule require testing of a chemical substance to develop appropriate test data if the Agency finds that:

> (A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
>
> (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
>
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or
>
> (B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,
>
> (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
>
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight of evidence approach in making section 4(a)(1)(A) findings in which both exposure and toxicity information are evaluated to make the finding that the chemical may present an unreasonable risk. For the first finding under section 4(a)(1)(B), EPA considers only production, exposure and release information to determine if there is or may be substantial production, and substantial release and/or significant or substantial human exposure. For the second finding under both sections 4(a)(1)(A) and 4(a)(1)(B), EPA examines toxicity and fate studies to determine if existing information is adequate either to determine or reasonably predict the effects of human exposure to, or environmental release of the chemical. In making the third finding that testing is necessary, EPA considers whether any ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would provide the necessary information.

EPA's process for determining when these findings apply is described in detail in EPA's first and second proposed test rules as published in the **Federal Register** of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300).

In evaluating the ITC's testing recommendations concerning ET and TMB, EPA considered all available relevant information including the following: information presented in the ITC's report recommending testing consideration; production volume, use, exposure and release information reported by manufacturers of ET and

TMB under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); and other published and unpublished data available to the Agency. The 8(a) rule covered only isomers of ET and 1,2,4-TMB; it did not require manufacturers of the $C_9$ fraction or the other TMB isomers to report. Based on its evaluation, as described in this proposed rule and the accompanying technical support document, EPA is proposing health effects testing requirements for the $C_9$ aromatic hydrocarbon fraction based on EPA's findings of substantial exposure to the $C_9$ fraction [section 4(a)(1)(B)]. No health effects testing of individual ET or TMB isomers is being proposed at this time. EPA has also concluded that no enviromental effects testing should be required for the $C_9$ fraction, ET, 1,2,4-, 1,2,3- or 1,3,5-TMB at this time.

## II. Proposed Rule

### *A. Profile*

1. *Ethyltoluenes.* Ethyltoluene (ET) occurs in three isomeric forms: 2-ET (*ortho*), 3-ET (*meta*) and 4-ET (*para*). Unless otherwise noted, the term "ethyltoluene" in this document refers to mixed ethyltoluenes, a substance containing all three isomers. ET (CAS No. 25550–14–5) is a colorless liquid readily soluble in most organic solvents, but relatively insoluble in water. ET is sufficiently volatile to enter the atmosphere, and is chemically stable under normal environmental conditions at room temperature. The individual isomers of ET are found in crude oil, gasoline, petroleum products, and have been detected in air and water, and in foods and natural products. ET, along with other nine-carbon aromatic hydrocarbons ($C_9$), is produced during the catalytic reforming of petroleum which is one of several processes involved in the production of gasoline. A portion of this $C_9$ stream is used as a solvent or a component in solvents. The remainder, estimated to be more than 90 percent, is used in gasoline blending. The solvents produced from the $C_9$ aromatic hydrocarbons are used in paint and varnish formulations, paint thinners, printing inks, pesticide formulations and, to a lesser extent, hydrocarbon lubricating oils for refrigerants. Solvents known to contain significant amounts of ET are Suresol 100, Aromatic 100 and Espersol 10.

Nearly pure ortho-ET is synthetically produced by Dow Chemical and used in the production of ortho-vinyltoluene which is used in fiber reinforced polyesters, vinyltoluene alkyds and copolymer resins. Conversion of ortho-ET to these products is nearly complete. Mobil synthesizes para-ET to produce para-vinyltoluene.

Total ET production (pure isomers plus that contained in the $C_9$ aromatic hydrocarbon fraction) is estimated to be between 30–50 billion pounds annually. All refiners of petroleum are manufacturers of the $C_9$ fraction. Despite the ITC's designation of ET and the existence of a CAS number, EPA has been unable to identify any product containing only mixed ET isomers. With the exception of the *ortho*-ET manufactured by Mobil, ET is found exclusively as one of the major components of the $C_9$ fraction.

2. *Trimethylbenzenes.* Trimethylbenzene (TMB) also occurs in three isomeric forms: 1,2,3-TMB, (CAS No. 526–73–8); 1,3,5-TMB, (CAS No. 108–67–8), and 1,2,4-TMB, (CAS No. 95–63–6). The 1,2,4-isomer is the most abundant and commercially is the most important isomer. 1,2,4-TMB is a clear, colorless liquid, readily soluble in organic solvents, but with low solubility in water. It is a stable compound under normal conditions, it undergoes typical electrophilic substitutions such as nitration, halogenation, sulfonation and alkylation, and is oxidized in the presence of catalysts.

Similar to ET, 1,2,4-TMB and other trimethylbenzenes are produced during catalytic reforming and compromise a major portion of the aromatic $C_9$ fraction. The uses of the $C_9$ fraction were discussed in the profile of ET.

1,2,4-TMB is separated from the aromatic $C_9$ reformate by the Koch Refining Company. Koch's 1,2,4-TMB production was in the range of 10 to 50 million lbs in 1977. Current volume appears to be in excess of 50 million lbs, with imports in 1981 of approximately 11.9 million lbs. Phillips Petroleum Company has reported production only of research quantities of 1,2,4-TMB since 1971. No synthetic process is currently used commercially for the production of 1,2,4-TMB.

Most of the isolated 1,2,4-TMB appears to be consumed as a raw material in the manufacture of trimellitic anhydride (approximately 50 million lbs/yr) which is subsquently used in the production of plasticizers, alkyd resins, unsaturated polyesters, and other industrial chemicals.

The other isomers of TMB are also present in the $C_9$ fraction. Some of the 1,3,5-isomer (mesitylene) is separated from the $C_9$ fraction and is used as an intermediate, primarily for production of 1,3,5-trimethyl-2,4,6-tris(3,5,-di-tert-butyl-4-hydroxybenzyl) benzene. This is produced by Ethyl Corporation and sold as Ethanox 330. It is an important antioxidant (noncoloring stabilizer) for plastics such as polypropylene, high-density polyethylene, polyamides, adhesives, specialty rubbers such as spandex fibers, and waxes.

The 1,2,3,-isomer (hemimellitene) is used principally to make a musk, similar to xylene musk. It is also oxidized to anhydro hemimellitic acid. No information is currently available to EPA on the quantities consumed through these uses, although those quantities are expected to be a small percentage of the total TMB production which is estimated to be approximately 30 billion pounds per year. EPA plans to require reporting under Section 8(a) of TSCA to obtain information on the production, exposure and release of 1,2,3- and 1,3,5-TMB. Should such reports indicate that there is substantial production of and exposure to these isolated isomers, EPA will reconsider the need for their testing as separate substances.

### *B. Findings*

The EPA is basing its proposed testing on the authority of section 4(a)(1)(B) of TSCA. EPA finds that:

1. There is no production of the mixed ETs aside from production of the $C_9$ aromatic hydrocarbon fraction. Likewise, although there is no evidence of substantial release of isolated TMB isomers to the environment, available data are adequate to predict that these isolated TMB isomers neither persist nor accumulate in the environment in sufficient quantity that would likely result in an unreasonable risk to the environment. The exposure of potential concern is to the $C_9$ fraction, not to mixed ETs, or isolated TMB isomers.

2. There are substantial amounts of the $C_9$ aromatic hydrocarbon fraction produced in the U.S. each year (approximately 80 billion pounds).

3. A substantial number of workers and consumers are exposed to the $C_9$ aromatic fraction through exposure to solvents and gasoline. EPA has concluded that this constitutes "substantial exposure" as that term is used in section 4 of TSCA.

4. There are insufficient data on neurotoxicity, reproductive effects, teratogenicity, and mutagenicity upon which to reasonably determine or predict the effects of exposure to the $C_9$ fraction, and testing is necessary to develop such data.

5. There are sufficent data on the subchronic effects and metabolism of the $C_9$ fraction; therefore, EPA is not proposing testing for these effects.

6. There are no data to indicate that exposure to 1,2,4-TMB or other isolated isomers of TMB is substantial and there

is no basis for finding that exposure to isolated isomers of TMB may present an unreasonable risk to human health from the effects mentioned by the ITC; therefore, EPA is not proposing testing of 1,2,4-TMB or otherr isomers separate from the proposed testing of the $C_9$ fraction.

7. Although the $C_9$ fraction is released to the environment in substantial quantities, available data are adequate to predict that this material neither persists nor accumulates in the environment in sufficient quantity that would likely result in an unreasonable risk to the environment. For this reason, EPA is not proposing that environmental effects testing be conducted at this time.

8. EPA is not proposing an oncogenicity bioassay based on the section 4(a)(1)(B) finding because EPA considers the required mutagenicity tests as an appropriate first tier for oncogenicity. However, EPA finds that if certain of the required mutagenicity tests produce positive results, this will be sufficient to indicate that the $C_9$ fraction may present an unreasonable risk of oncogenic effects. In such circumstances, EPA finds that unless a 2-year bioassay has been initiated, there will be insufficient data to predict oncogenicity, and testing will be necessary to develop oncogenicity data.

The ET and TMB technical support documents are available from the Industry Assistance Office. The ITC's recommendations and EPA's proposed tests are summarized below.

| Test | ITC recommendation | | EPA proposed testing |
|---|---|---|---|
| | ET | 1,2,4-TMB[1] | $C_9$ |
| Health effects: | | | |
| Subchronic | X | X | No testing. |
| Neurotoxicity | | X | X. |
| Reproduction | | X | X. |
| Teratogenicity | | X | X. |
| Mutagenicity | X | | X. |
| Metabolism | X | | No testing. |
| Carcinogenicity | | | X (if mutagenicity test results are positive). |
| Environmental effects: | | | |
| Acute and chronic (fish and invertebrates). | X | X | No testing. |
| Aquatic and terrestrial plants | X | X | Do. |
| Bioconcentration | X | X | Do. |
| Environmental fate: | | | |
| Aquatic persistence and transformation. | X | X | Do. |
| Atmospheric persistence and transformation. | X | X | Do. |

[1] No specific testing recommendations were made for 1,2,3-TMB and 1,3,5-TMB.

### C. Test Substance

EPA is proposing that a synthetic $C_9$ petroleum fraction, composed of specific concentrations of mixed isomers of ET, and 1,2,4-, 1,2,3- and 1,3,5-TMB, in such proportion that it is representative of a typical aromatic hydrocarbon fraction produced during the refining of crude petroleum, be formulated and used as the test substance. EPA is requesting comment on the range of composition of the $C_9$ fraction, on whether a single test substance can adequately represent the $C_9$ fraction and, what the composition of the test substance should be. Comments are also requested on the use of a representative composite sample of actual $C_9$ fractions gathered from industrial sources for use as the test substance.

### D. Persons Required To Test

Section 4(b)(3)(B) specifies that the activities for which the Administrator makes section 4(a) findings (manufacturing, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). All petroleum refiners located in the U.S. are considered "manufacturers" of the $C_9$ petroleum fraction, as are importers (if any) of the $C_9$ fraction. Processors are required to test if the findings are based on processing. (Section 3(7) of TSCA, defines "process" as the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce.) Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal. Because EPA has found that the use of the $C_9$ fraction may give rise to substantial exposure, EPA is proposing that persons who manufacture or process, or who intend to manufacture or process, the $C_9$ aromatic hydrocarbon fraction at any time from the effective date of this test rule to the end of the reimbursement period be subject to the rule. The end of the reimbursement period will be 5 years after the submission of the final report required under the test rule.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from that requirement. As discussed in Unit II.F, EPA expects that manufacturers will conduct testing and processors will ordinarily be exempted from testing.

### E. Development and Adoption of Study Plans

EPA proposed generic test methodology requirements (generic test standards) for various health effects in the **Federal Register** of May 9, 1979 (44 FR 27334) and of July 26, 1979 (44 FR 44054). In response to concerns about rigid generic test methodology requirements, EPA changed its approach for providing test standards for TSCA section 4 test rules and has instead issued generic test methodology guidelines to replace previously proposed generic test methodology requirements. The guidelines have been published by the National Technical Information Service (NTIS) under publication number PB 82-232984. Test methodology requirements for particular chemicals will be developed on a case-by-case basis. Good Laboratory Practice (GLP) standards will continue to be promulgated as generic requirements. (See the **Federal Register** of March 26, 1982; 47 FR 13012.)

Under the new approach, test rule development will be a two-phase process. In Phase I, test rules will be promulgated for individual chemicals specifying the health or environmental effects characteristics for which test data are to be developed. In Phase II, following promulgation of a test rule, those persons subject to the rule will be required to develop study plans for the development of data pertaining to the effects and characteristics specified in the rule. For guidance in preparing study plans, it is recommended that the TSCA Health Effects Test Guidelines, published by NTIS (PB 82-232984), be consulted. Additional guidance may be obtained from the Organization for Economic Cooperation and Development (OECD) Test Guidelines

and the Pesticide Assessment Guidelines, published by NTIS (PB 83-153916).

Manufacturers who sponsor testing must submit their study plans to EPA within 90 days from the effective date of the test rule. After an opportunity for public comment, EPA will issue a rule adopting the study plans as proposed or modified. The approved and adopted study plans, including the names and addresses of laboratories conducting the tests, will become the enforceable test requirements and will serve as the chemical specific test standards for the test rule. Testing will also be subject to EPA's generic Good Laboratory Practice (GLP) standards. Modifications to the adopted study plans may be made only with EPA approval.

For the purposes of announcing the carcinogenicity test if it is needed, the Agency will publish a Notice in the **Federal Register** announcing the receipt of the mutagenicity test data, EPA's evaluation of the results of the testing, and the need for the carcinogenicity testing. This Notice will then start the Phase II portion of the rule requiring carcinogenicity testing. Persons subject to the rule will follow the existing mechanisms for submission of study plans within the allowed time.

EPA intends to issue a procedural rule outlining the details of the two-phase rulemaking process, which will apply to the test rule for the $C_9$ aromatic hydrocarbon fraction and all other test rules. Information on this proposed procedure appears in the July 18, 1980 **Federal Register** (45 FR 48512), the March 26, 1982 **Federal Register** (47 FR 10312), and the April 29, 1982 **Federal Register** (47 FR 18390). If there are significant changes in the final procedural rule which will be issued before the $C_9$ hydrocarbon mixture rule is promulgated, EPA may allow a short period of supplementary comment on the $C_9$ aromatic hydrocarbon proposal.

*F. Exemption Procedures*

Within 30 days after the effective date of the final rule, each manufacturer of the $C_9$ aromatic hydrocarbon fraction must either (1) notify EPA that it intends to conduct or sponsor testing and to submit study plans for the required tests, or (2) apply for an exemption on a belief that testing will be performed by others. Study plans must be submitted within 90 days after the effective date of this rule. If no manufacturer notifies EPA of its intent to sponsor testing, EPA will inform manufacturers that their exemption will not be granted. They will, nevertheless, have the opportunity to submit study plans in compliance with this rule until 90 days from the effective date of this rule.

Processors of the $C_9$ fraction will not be required to apply for an exemption, submit study plans or conduct testing unless manufacturers fail to sponsor the required tests. If manufacturers do not submit study plans and conduct testing, EPA will issue a notice in the **Federal Register** requiring processors to submit notices of intent to test or apply for an exemption, to submit study plans and to conduct testing. No exemptions will be granted until a study plan for each of the required tests is received and approved.

EPA is not proposing to require equivalence data as a condition for exemption from the proposed testing of the $C_9$ fraction. EPA will require for testing a mixture that is representative of the $C_9$ fractions to which persons are most commonly exposed. comment is being solicited in this rulemaking on the appropriate makeup of the representative $C_9$ fraction.

EPA proposed exemption procedures for section 4 test rules in the **Federal Register** of July 18, 1980 (45 FR 48512). EPA intends to issue these procedures as a final rule shortly. If there are significant changes in the exemption procedures, EPS may allow a short period of supplementary comment on the $C_9$ aromatic hydrocarbon proposal.

*G. Reporting Requirements*

EPA is proposing that all data be reported in accordance with TSCA Good Laboratory Practice (GLP) standards. Such standards were proposed in the **Federal Register** of May 9, 1979 (44 FR 28369) and November 21, 1980 (45 FR 77332) and will appear in final form in 40 CFR Part 792. EPA has reviewed public comments on the proposed GLP Standards and is now developing final GLP standards. The final GLP standards will apply to this rule.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. These deadlines will be established in the Phase II rulemaking in which study plans are approved.

TSCA section 14(b)(I)(A)(ii) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the **Federal Register** as required by section 4(d).

*H. Enforcement Provisions*

Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA. The Agency considers that failure to comply with any aspect of a section 4 rule may be a violation of sections 15(1) and 15(3) of TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *." The Agency considers a testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory audits/inspections will be periodically conducted in accordance with the authority and procedures outlined in TSCA section 11 by authorized representatives of the EPA for the purpose of determining compliance with any final rule issued in this proceeding. 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 evaluations thereof, and that the studies are being conducted according to TSCA GLP standards and the test standards adopted in the rule.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing after the deadlines for such submissions. Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to one year. Other remedies are available to EPA under sections 7 and 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4 and the seizure of chemical substances

manufactured or processed in violation of the rule.

Individuals, as well as corporations, could be subject to enforcement actions. Section 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported.

### III. Issues For Comment

1. Is the $C_9$ fraction the appropriate test substance? Can a single $C_9$ substance or mixture be selected which will be representative, for toxicological purposes, of the $C_9$ fraction to which persons are exposed through exposure to solvents and gasoline? If so, what should the specifications be for such substance or mixture? If not, what substances should be selected for testing and why? Should a commercial $C_9$ fraction be used for testing instead of a synthetic mixture?

2. Can a negative result (or a high no-observed-effect-level) on the $C_9$ fraction be used to make reasonable predictions that the individual ET and TMB isomers will not present an unreasonable risk of that effect?

3. Should the testing of the individual isomers be required for any of the tests? If so, which isomers and which tests?

4. Should oncogenicity testing of the $C_9$ fraction be required only if selected mutagenicity tests produce non-negative results, or should oncogenicity testing be required immediately on the basis of the TSCA section 4(a)(1)(B) findings?

5. What should the routes of exposure for the test substance be?

### IV. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for test rules go through a Level I analysis. This consists of evaluating each chemical or chemical group on four principal market characteristics: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations. The results of the Level I analysis, along with a consideration of the cost of the required tests, indicate whether the possibility of a significant adverse economic impact exists. Where the indication is negative, no further economic analysis is done for that chemical substance or group. However, for those chemical substances or groups where the Level I analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted. This Level II analysis attempts to predict more precisely the magnitude of the expected impact.

For a more complete and thorough discussion of the methodology used to conduct economic analyses of this test rule, see the *Level I Economic Impact Analysis for Ethyltoluene and 1,2,4-Trimethylbenzene* (EPA Contract No. 68–01–6630).

Total testing costs for this proposed rule are estimated to range from $513,800 to $1,537,900. The annualized cost range is $133,100 to $398,500 over 15 years based on a 25 percent cost of capital. Because of the huge production volume of the $C_9$ petroleum fraction, the unit test costs (i.e., the cost per pound) are negligible.

The potential for adverse economic effects resulting from testing requirements for the $C_9$ fraction is low for the following reasons:

The overall demand for the $C_9$ fraction is relatively inelastic due to: (1) The superior octane qualities of the aromatic $C_9$ fraction, (2) the relatively inelastic demand for gasoline, and (3) the price advantages of aromatic solvents containing unisolated ethyltoluene.

The estimated unit test costs are negligible; approximately 0.0004 cents per pound of the $C_9$ fraction in the upper bound case.

### V. Availability of Test Facilities and Personnel

Section 4(b)(1) requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and test programs negotiated with industry in place of rulemaking. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," can be obtained through the National Technical Information Service (NTIS), Springfield, Virginia (Publication No. 82–140773).

The conclusions reached in the laboratory availability study were: (1) The chemical testing industry's anticipation of increased testing requirements has prompted the rapid expansion of testing facilities in recent years; (2) currently, excess capacity exists in all major testing areas, and surveyed laboratories indicated they could perform about 29 percent more testing; (3) measurable industry concentration exists, but it is not enough to restrict market entry or control key resources; and (4) currently, capital and professional manpower are the most constraining resources on industry expansion of testing facilities. Capital is understandably a cyclical constraint. The constraint imposed by a shortage of professional personnel can be long-term because of the lengthy period required for professional preparation; however, current personnel numbers appear adequate relative to present testing levels.

On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing required in this proposed rule.

### VI. Evironmental Impact Statement

EPA is not required to prepare Environmental Impact Statements (EIS) under the National Environmental Policy Act (NEPA), 41 U.S.C. 4321, for test rules. EPA has determined that voluntary preparation of an EIS is not appropriate for regulations issued under section 4 of TSCA. See the preamble to the Agency's rules for compliance with NEPA published in the **Federal Register** of November 6, 1979 (44 FR 64174).

### VII. Public Meetings

If persons wish to present comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting on August 8, 1983 in Washington, D.C. This meeting is scheduled after the deadline for submission of written comments, so that issues raised in the written comments can be discussed by EPA and the public commenters. Information on the exact time and place of the meeting will be available from the Industry Assistance Office. Toll Free: (800–424–9065). In Washington, D.C.: 554–1404. Outside the U.S.A.: (Operator—202–554–1404).

Persons who wish to attend or present comments at the meeting should call the Industry Assistance Office by July 7, 1983. While the meeting will be open to the public, active participation will be limited to those persons who have arranged to present comments and to designated EPA participants. Attendees should call the Industry Assistance Office before making travel plans because the meeting will not be held if members of the public do not wish to make oral comments.

The Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

### VIII. Public Record

EPA has established a public record for this rulemaking, docket number OPTS-42034, which is available for inspection in the OPTS Reading Room, Rm. E-107, 401 M St. SW., Washington, D.C., from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. This record includes the 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.

The Public Record shall include the following information:

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice of Proposed Rule on $C_9$ Aromatic Hydrocarbon Fraction and Response to the ITC on ET and 1,2,4-, 1,2,3- and 1,3,5-TMB

(b) Notice containing the ITC designation of ET and 1,2,4-TMB to the Priority List.

(c) Notice containing the ITC recommendation of the other trimethylbenzenes to the Priority List.

(d) Notices relating to EPA's health effects test guidelines and TSCA GLP standards.

(e) Notice of Proposed Rule on Exemption Policy and Procedures.

(f) Notice of Proposed Rulemaking on Reimbursement Policy and Procedures.

(g) Notice of change in Test Standards Policy and Test Rule Development Process.

(2) Support Documents: consisting of:

(a) ET and TMB Technical support documents

(b) Economic analysis support document

(3) Minutes of informal meetings

(4) Communications before proposal consisting of:

(a) Written public comments

(b) Summaries of telephone conversations

(5) Reports-published and unpublished factual materials, including contractors' reports.

### IX. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of preparing 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. First, the estimated annual cost of the testing proposed is less than $398,500 over the testing and reimbursement period. Second, because the cost of the required testing will be distributed over a large production volume, the rule will have only very minor effects on users' prices for these chemicals, even if all tests cost were passed on. Finally, taking into account the nature of the market for the $C_9$ fraction, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic effects of any type as a result of this rule.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

### X. 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. Small manufacturers or processors will not perform testing themselves, or participate in the organization of the testing effort.

2. Small manufacturers or processors will experience only very minor costs in securing exemption from testing requirements.

3. Small manufacturers and processors are unlikely to be affected by reimbursement requirements.

The basis for this decision is the same as that discussed in detail in the **Federal Register** of June 5, 1981 (46 FR 30300).

### XI. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (44 U.S.C 3501 *et seq.*) authorizes the Director of OMB to review certain information collection requests by Federal agencies. The test rule proposed in this notice, if promulgated, could result in the submission of several types of information related to the required testing, including study plans and final reports for each test required by persons sponsoring the tests. For the reasons set out in the **Federal Register** of June 5, 1981 (46 FR 30300), EPA believes that the test rule contained in this notice does not constitute an information collection request as defined in the Paperwork Reduction Act. An information collection request subject to the provisions of the Paperwork Reduction Act might be triggered by the exemption provisions related to this test rule. The need for such information will be reviewed by the Office of Management and Budget as part of its review of EPA's rule on TSCA section 4(c) exemptions.

### List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous material, Chemicals.

Dated: May 10, 1983.

**Lee L. Verstandig,**

*Acting Administrator.*

## PART 799—IDENTIFICATION OF SPECIFIC CHEMICAL SUBSTANCES TESTING REQUIREMENTS

Therefore, it is proposed that a new § 799.1625 be added to Part 799 Chapter I of 40 CFR , to read as follows:

### Subpart A—[Reserved]

### Subpart B—Specific Chemical Testing

#### § 799.1625 $C_9$ aromatic hydrocarbon fraction.

(a) *Identification of test substance.* (1) A synthetic $C_9$ mixture consisting of *ortho-*, *meta-* and *para-*ethyltoluene, 1,2,4-, 1,2,3- and 1,3,5-trimethylbenzene that is representative of a typical $C_9$ aromatic petroleum fraction obtained from the reforming of crude petroleum shall be prepared.

(2) A synthetic $C_9$ mixture as described above shall be used as the test substance in all tests.

(b) *Persons required to test.* (1) All persons who manufacture (includes import), process, or intend to manufacture or process the $C_9$ aromatic product of petroleum refining (hereafter known as manufacturers and processors as defined in sections 3(7) and 3(10) of TSCA) from the effective date of this rule to the end of the reimbursement period shall submit study plans and conduct tests and submit data as specified by this part.

(2) Any person subject to the requirements of this section may apply to EPA for an exemption from study plan submission, testing, and data submission. No later than 30 days after the effective date of this rule, each manufacturer of the $C_9$ fraction must notify EPA by letter of an intent either to submit a proposed study plan or to be exempted from testing for each test or study required in this rule.

(3) If manufacturers submit study plans, conduct testing, and submit data in a satisfactory manner, processors will be given an automatic exemption by EPA. If manufacturers fail to submit satisfactory study plans or data, all persons who process or intend to process the $C_9$ fraction from the effective date of this rule to the end of the reimbursement period shall be directed in a special **Federal Register** Notice to submit study plans, and to conduct tests

and submit data as specified by this Part or be in violation of this rule.

(c) *Study plans*—(1) *Testing.* Testing shall be performed using a study plan submitted and approved in accordance with 40 CFR Part 770. All raw data, documentation, records, protocols, specimens and reports generated as a result of a study shall be developed, reported and retained in accordance with the EPA Good Laboratory Practices (GLP) standards in 40 CFR Part 792. These data and other reports shall be made available during an inspection or submitted to EPA upon request by EPA or its authorized representative.

(2) *Submission.* (i) Manufacturers of the $C_9$ fraction who indicate they will perform testing must submit proposed study plans on or before 90 days after the effective date of this rule. Only one set of study plans should be prepared and submitted by persons who are jointly sponsoring testing.

(ii) If, by the date specified in paragraph (b)(2) of this section, no manufacturer files a letter of intent to submit a proposed study plan for any test required by this rule, EPA will so notify the manufacturers to assure them an opportunity to submit study plans and conduct testing in compliance with this rule. If no manufacturer intends to conduct testing, EPA will publish a **Federal Register** notice of this fact and then (A) no later than 30 days after publication of such a notice, each processor must notify EPA by letter of its intent either to submit a proposed study plan for each test that will not be covered by a manufacturer's study plans or to be exempted from testing and (B) processors who indicate they will perform testing must submit proposed study plans on or before 90 days after publication of such a notice.

(iii) Manufacturers who do not notify EPA of their intent, either to submit a proposed study plan or to be exempted from testing for each test or study for which testing is required in this rule, will be considered in violation of the rule beginning on the 31st day after the effective date of the rule. Manufacturers who indicate they will perform testing and which do not submit proposed study plans on or before 90 days after the effective date of this rule will be considered in violation of the rule beginning on the 91st day after the effective date of this rule. Each processor who fails to submit a letter of intent to submit a study plan or to request an exemption when required will also be considered in violation of this rule beginning on the 31st day after publication of the notice described in paragraph (c)(2)(ii) of this section.

(iv) If no study plan is proposed for each test or study required in this rule, every manufacturer and every processor of such chemicals will be in violation of TSCA beginning on the 91st day after the publication of the notice described in paragraph (c)(2)(ii) of this section, until such a study plan is submitted by an appropriate sponsor.

(3) *Content.* (i) All study plans are required to contain the following information:

(A) Identity of the test rule and the specific test requirements of that rule to be covered by the study plan.

(B)(*1*) The names and addresses of the test sponsors.

(*2*) The names and addresses of the responsible administrative officials and project manager(s) in the principal sponsor's organization.

(*3*) The name, address and telephone number of the appropriate individual for oral and written communications with EPA.

(*4*)(*i*) The name and address of the testing facility, including responsible administrative officials and project manager(s) responsible for this testing.

(*ii*) Brief summaries of the training and experience of each professional involved in the study including study director, veterinarian(s), pathologist(s), and pathology assistants.

(C) Identity and data on the mixture or substance being tested including appropriate physical constants, spectral data, chemical analysis and stability under test and storage conditions.

(D) Study protocols including rationale for: species/strain selection; dose selection (and supporting data); route(s) or method(s) of exposure; incubation temperature; a description of diet to be used and its source, including nutrients and contaminants and their concentrations; a description of culture medium and its source; and a summary of expected spontaneous chronic disease, genealogy, and life span.

(E) Schedule for initiation and completion of major phases of long-term tests; schedule for submission of interim progress and final reports to EPA.

(ii) Information given under paragraph (c)(3)(i)(B)(*4*) of this section is not required in proposed study plans if the information is not available at the time of submission; however, the information must be submitted before the initiation of testing.

(4) *Adoption.* Upon receipt of proposed study plans, EPA will publish a notice in the **Federal Register** requesting comments on the ability of the study plans to ensure that data from the tests are reliable and adequate. EPA will provide a 45-day comment period, and will provide an opportunity for an oral presentation on the request of any person. EPA may extend the comment period if it appears from the nature of the issues raised by EPA's review or public comments that further comment is warranted. Following the close of the comment period, EPA will publish a final rule adopting the study plans as proposed or modified as test standards for the testing of the $C_9$ fraction.

(5) *Modification of study plans during conduct of study*—(i) *Application.* Any test sponsor who wishes to modify the adopted study plan for any test required under this rule must submit an application in accordance with this section. Application for modification shall be made in writing or by phone to the Chief, Test Rules Development Branch, with written confirmation to follow as soon as feasible. Applications must explain why the modification is necessary.

(ii) *Adoption.* To the extent feasible, EPA will seek comment on all significant changes in study plans. EPA will issue a notice in the **Federal Register** requesting comments on requested modifications in accordance with section 4(b)(5) of TSCA. However, EPA will act on the requested modification without seeking pubic comment (A) if EPA believes that an immediate modification to a study plan is necessary in order to preserve the accuracy of an on-going study or (B) if EPA determines that a modification clearly does not pose any significant, substantive issues. EPA will notify the sponsor of the Agency's approval or disapproval. When the Agency approves a modification, it will publish a notice in the **Federal Register** indicating that the study plan has been modified.

(d) *Health Effects Testing*—(1) *Mutagenic effects—Chromosomal aberrations.* (i) *Required testing.* (A) An *in vitro* cytogenetics test shall be conducted with the synthetic $C_9$ mixture as specified in paragraph (a) of this section.

(B) An *in vivo* cytogenetics test shall be conducted if the synthetic $C_9$ mixture produces a negative result in the *in vitro* cytogenetics test.

(C) A dominant lethal assay shall be conducted for the synthetic $C_9$ mixture if it produces a positive result in the *in vitro* or *in vivo* cytogenetics test.

(D) A heritable translocation assay shall be conducted with the synthetic $C_9$ mixture if it produces a positive result in the dominant lethal assay.

(E) Further testing for chromosomal aberrations is not required for the synthetic $C_9$ mixture if it produces a negative result in the *in vivo*

cytogenetics test or the dominant lethal assay.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Health Effects Test Guidelines for Chromosomal Effects, published by NTIS (PB 82–232984), be consulted. Additional guidance may be obtained from the OECD Test Guidelines for Genetic Toxicology and the Pesticide Assessment Guidelines, published by NTIS (PB 83–153916).

(2) *Mutagenic effects—Gene Mutation*—(i) *Required testing.* (A) A *Salmonella* micorsomal assay shall be conducted on the synthetic $C_9$ mixture specified as the test substance, both with and without activation.

(B) A DNA damage assay shall be conducted.

(C) A sister chromatid exchange (SCE) assay shall be conducted.

(D) A gene mutation in mammalian cells in culture assay shall be conducted.

(E) A second gene mutation in mammalian cells in culture assay, using a different cell line from that used in the first assay, shall be conducted if the synthetic $C_9$ mixture produces a negative result in the first gene mutation in cells in culture assay, specified by paragraph (d)(2)(i)(D) of this section, coupled with positive results in at least two of the following three tests: the *Salmonella* microsomal, DNA damage or SCE assays.

(F) The synthetic $C_9$ mixture shall be tested in a *Drosophila* sex-linked recessive test, in the event it produces a positive result in the *Salmonella* microsomal assay, DNA damage assay, SCE assay or a gene mutation in cells in culture assay.

(G) A mouse specific locus assay shall be conducted with the synthetic $C_9$ mixture if it produces a positive result in the *Drosophila* sex-linked recessive test.

(H) Further testing for gene mutations is not required for the synthetic $C_9$ mixture if it produces a negative result in the *Drosophila* sex-linked recessive test.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Health Effects Test Guidelines for Gene Mutations and DNA Effects, published by NTIS (PB 82–232984), be consulted. Additional guidance may be obtained from the OECD Test Guidelines for Genetic Toxicology, and the Pesticide Assessment Guidelines, published by NTIS (PB 83–153916).

(3) *Carcinogenicity*—(i) *Required testing.* A 2–year inhalation oncogenicity bioassay shall be conducted with the synthetic $C_9$ mixture unless it produces negative results in all of the following tests: *In vitro* cytogenetics test, *in vivo* cytogenetics test, first gene mutation in cells in culture assay, second gene mutation in cells in culture assay (if required) and *Drosophila* sex-linked recessive test.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Health Effects Guidelines for Chronic Exposure-Oncogenicity published by NTIS (PB 82–232984), be consulted. Additional guidance may be obtained from the OECD Test Guidelines for Health Effects Section #451 and the Pesticide Assessment Guidelines, published by NTIS (PB 83–153916).

(4) *Teratogenicity*—(i) *Required testing.* An inhalation teratogenicity study shall be conducted with the synthetic $C_9$ mixture.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Health Effects Test Guidelines for Specific Organ/Tissue Toxicity-Teratogenicity, published by NTIS (PB 82–232984), be consulted. Additional guidance may be obtained from the OECD Test Guidelines for Health Effects, and the Pesticide Assessment Guidelines, published by NTIS (PB 83–153916).

(5) *Reproductive Effects*—(i) *Required testing.* A two-generation inhalation reproductive effects study shall be conducted with the synthetic $C_9$ mixture.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Health Effects Test Guidelines for Specific Organ/Tissue Toxicity-Reproduction/Fertility Effects, published by NTIS (PB 82–232984), be consulted. Additional guidance may be obtained and the Pesticide Assessment Guidelines, published by NTIS (PB 83–153916).

(6) *Neurotoxicity*—(i) *Required testing.* The neurotoxicity test battery shall consist of a 90-day subchronic inhalation exposure incorporating the following tests:

(A) A neuropathology test shall be conducted with the synthetic $C_9$ mixture.

(B) A motor activity test shall be conducted with the synthetic $C_9$ mixture.

(C) A functional observation battery shall be conducted with $C_9$ mixture.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Health Effects Test Guidelines for Neurotoxicity, published by NTIS (PB 82–232984), and the Pesticide Assessment Guidelines (NTIS; PB 83–153916) be consulted.

(Sec. 4(e) of TSCA, Pub. L. 94–469, 90 Stat. 2003 et seq.; 15 U.S.C. 2601 *et seq.*)

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