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REGISTRATION

40 CFR Part 798

(OPTS 42030; TSH-FRL 2343-6)

Mesityl Oxide; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

**SUMMARY:** In the Fourth Report of the Interagency Testing Committee (ITC) submitted to the Administrator in April 1979 and published in the Federal Register of June 1, 1979 (44 FR 37866), the ITC designated mesityl oxide (MO) for priority consideration for health effects testing. The ITC recommended that testing of MO be considered for carcinogenicity, mutagenicity, teratogenicity, and other chronic effects with emphasis on blood disorders. The ITC also recommended that EPA consider requiring an epidemiology study. The ITC, in its designation of MO, cited production and exposure figures and structure activity relationships which implied that MO could potentially cause carcinogenic and/or mutagenic effects. Reported health effects were the basis for recommending chronic tests and epidemiology, and lack of information was the basis for recommending teratogenic effects. Under section 4 of the Toxic Substances Control Act (TSCA), EPA is proposing that manufacturers and processors of MO test this chemical for chronic toxicity with special emphasis on blood disorders and for mutagenicity, including gene mutation and cytogenetic tests. In addition, EPA is proposing that MO be tested for oncogenicity if the results obtained in the mutagenicity tests are positive. EPA is not proposing that MO be tested for teratogenicity because there is no evidence to suggest that MO might produce teratogenic effects. EPA is not proposing

iology because an end-point has been identified which could be the basis for such a study. Testing will be performed according to protocols established in a subsequent rulemaking.

This notice constitutes EPA's response to the Interagency Testing Committee's designation of MO as a priority candidate for testing.

**DATE:** Submit written comments on or before September 6, 1983. Make requests to submit oral comments by August 19, 1983. EPA will hold a public meeting on September 19, 1983, on this rule in Washington, D.C. For further information on arranging to speak at the meeting see unit VI of this preamble.

**ADDRESS:** Address written comments identified by the document control number (OPTS-42030) 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 INFORMATION CONTACT:**

McCarthy, Director, TSCA Public Information Office (TS-799), 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:** All specific chemical testing requirements established under section 4(a) of TSCA are being consolidated in the new 40 CFR Part 799 being established in this document. Specific chemical testing rules which initially were proposed under 40 CFR Part 773 will be integrated into the organizational scheme for Part 799 when finalized.

**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 MO for priority consideration in its Fourth Report, submitted to EPA in April 1979, and published in the Federal Register of June 14, 1979 (44 FR 31866). The ITC

recommended that MO be considered for testing following health effects testing: carcinogenicity, mutagenicity,

teratogenicity, and other chronic effects: it also recommended an epidemiology study. This notice constitutes EPA's response to the ITC's designation of MO as a priority candidate for testing.

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 considers both exposure and toxicity information to make the finding under section 4(a)(1)(A) 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 substantial production and substantial exposure or release. 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 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 be capable of developing the necessary information.

EPA's approach to determining when these findings can be made 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 48524) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) finding is discussed in 45 FR 48528 and the section 4(a)(1)(B) finding is discussed in 46 FR 30300.

EPA is proposing under section 4(a)(1)(A) health effects testing requirements for MO based on EPA's findings for this chemical.

**II. Proposed Rule**

**A. Profile**

Mesityl oxide, or 4-methyl-3-pentene-2-one, CAS no. 141-87-7, is a colorless, oily liquid that vaporizes at room temperature sufficiently to produce a marked odor of peppermint. MO is produced from acetone via diacetone alcohol. It may be further reacted to produce methyl isobutyl ketone (MIBK) and methyl isobutyl carbinol (MIBC) either simultaneously or sequentially. Each firm that produces MO to be marketed as such also obtains MO as a secondary coproduct of phenol. Each firm also produces derivative MIBK and many have the capacity to produce MIBC.

MO is primarily used as an intermediate in the manufacture of MIBK. Some production of MIBC also comes from MO via MIBK. End-product use of MO constitutes only about 18 percent of MO production. Its main end-product use is reportedly as a solvent in lacquer and lacquer thinners. Very little current actual use of MO in end-products can be documented although it has been reported as a constituent of paint removers and inks. Production in 1980 for non-captive use/storage was 31 million pounds, while captive production (estimated from the quantity of MIBK/MIBC produced) was 170 million pounds.

### B. Findings

The EPA is basing its proposed testing on the authority of section 4(a)(1)(A) of TSCA. EPA finds that 31 million pounds of MO are produced annually potentially for use as an end product and that between 500 and 8,000 workers are exposed in all aspects of the manufacture, processing, distribution and use of MO. An additional amount of MO is produced as a transient intermediate in the production of MIBK. The amount is approximately 190 million pounds per year, based on an average of reported MIBK production for 1980 and 1981. EPA believes that these figures indicate a potential for human exposure which is sufficient to support a "may present an unreasonable risk" finding in those situations in which there is evidence that MO is likely to result in a health effect. EPA does not believe that this information constitutes substantial exposure as that term is used in section 4(a)(1)(B).

The 4(a)(1)(A) findings for specific health effects are as follows:

1. EPA finds that the manufacture, processing, and use of MO may present an unreasonable risk of injury to human health due to chronic effects because EPA has found that there are existing animal studies which show the potential of MO to cause chronic health effects. In addition a report has been published that found chronic health effects in a population of workers exposed to MO. In particular, changes in blood parameters were found in both humans and animals. Furthermore, the manufacture, processing, and use of MO may present an unreasonable risk from mutagenic effects. MO possesses a chemical structure which includes an alpha-beta unsaturated carbonyl group. Such a group may give the molecule that possesses it an ability to react with specific groups present in DNA molecules of living organisms. If such reactions occur they may alter the DNA molecule and result in cellular and/or genetic damage which may be expressed as mutagenic effects.

EPA also finds that, if certain mutagenicity tests give positive results, this fact, combined with structural data, will indicate that MO may present an unreasonable risk of carcinogenic effects.

2. EPA also finds that there are insufficient animal and human data to determine reasonably or predict the chronic and mutagenic effects of MO. The finding of potential unreasonable risk of mutagenic effects is based on structure activity relationships, and there are no test results to verify it. The data which show chronic effects are

limited in scope and are inconclusive as to effects.

The conditional "may present" finding for carcinogenicity, would be based on structure and short-term mutagenicity tests; however, this information would be insufficient to verify the carcinogenic potential of MO.

3. EPA finds that testing of MO for chronic toxicity and mutagenicity is necessary to develop data needed to evaluate reasonably the health risks posed by exposure to MO. In addition, testing for carcinogenicity will be required if results of mutagenic testing indicate a potential for carcinogenic activity.

Based on these findings, the Agency is proposing a 90-day subchronic test in animals with special emphasis on blood findings. As reported in the OTS Workshop on Subchronic Toxicity Testing (EPA-560/11-80-028) subchronic toxicity studies can serve as surrogates for full chronic toxicity tests. Therefore, for the purposes of TSCA section 4, the Agency will accept a properly conducted subchronic 90-day study with full histopathology as a basis for predicting the chemical's chronic effects.

The Agency is also proposing a battery of short-term tests for gene mutation and chromosomal aberration which it believes will provide an adequate basis for determining whether MO does possess mutagenic activity.

In addition, the Agency will use the gene mutation in somatic cells assay, the *Drosophila melanogaster* sex-linked recessive lethal test, the *in vitro* cytogenetics assay and the *in vivo* cytogenetics assay to determine the need for oncogenic study of MO. If any one of these end-points, when tested, indicates that MO has mutagenic potential as defined by the OTS test guidelines, then it is the Agency's view that MO may present an unreasonable risk of cancer, and because data are unavailable, testing will be required as stated in this proposed rule.

The Agency is not proposing epidemiology because it believes that no end-point has been sufficiently well-defined to make a finding for unreasonable risk to humans.

EPA is not proposing testing for teratogenic effects, because at the present time there is no evidence to suggest that MO may be a teratogen, and therefore a finding of potential unreasonable risk cannot be made for this effect.

EPA does not find that the number of people exposed to MO is substantial or involves a significant segment of the population or that it enters the environment in substantial quantities, and consequently the Agency cannot

make a 4(a)(1)(B)(i) finding upon which to require additional testing.

The analyses on which the above findings are based are presented in the MO Support Document which is available from the TSCA Assistance Office. The ITC recommendations and EPA's proposed testing requirements are summarized as follows:

Test or study	ITC recommendation	EPA proposal
Carcinogenicity	X	X
Mutagenicity	X	X
Teratogenicity	X	X
Chronic effects	X	X
Epidemiology	X	X

<sup>1</sup> If triggered.

<sup>2</sup> Subchronic proposed in lieu of full chronic.

### C. Test Substance

EPA is proposing that MO of 97 percent purity be used as the test substance because this grade is readily available commercially and is the material to which worker would be exposed.

### D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which the Administrator makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determines 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"). Processors are required to test if the findings are based on processing. 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 manufacturing, processing, and use of MO give rise to exposures that may lead to an unreasonable risk, EPA is proposing that persons who manufacture or process, or who intend to manufacture or process, this chemical 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 ordinarily will be 5 years after the submission of the last final report required under the test rule. As discussed in Unit F of this Preamble, EPA expects that manufacturers will conduct testing and that processors will ordinarily be exempted from testing.

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

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.

#### *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 the Federal Register of July 28, 1979 (44 FR 44054). In response to concerns about rigid generic test methodology requirements, EPA has changed its approach for providing test standards for TSCA section 4 test rules and has 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 82-232964. Good Laboratory Practice (GLP) standards will continue to be promulgated as required. (See the Federal Register of March 28, 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, and the reporting requirements. 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 82-232964), be consulted. Additional guidance may be obtained from the Organization for Economic Cooperation and Development (OECD) Test Guidelines and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Pesticide Assessment Guidelines published by NTIS (PB 83-153916 for Hazard Evaluation: Human and Domestic Animals).

Sponsors 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 final rule adopting the study plans as proposed or modified. The approved and adopted study plans 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 GLP standards. Modification to the adopted study plans can be made only with EPA approval.

EPA intends to issue a procedural rule which will set out the details of the two-phase rulemaking process. That procedural rule will apply to the test rule for MO and all other test rules. Information on this proposed procedure appears in the July 18, 1980 Federal Register (45 FR 48512), which describes the proposed exemption policy and procedures; in the March 26, 1982 Federal Register (47 FR 10312) which provides the policy statement on the test rules development process; and in the proposed test rules for diethylenetriamine in the April 29, 1982 Federal Register (47 FR 18390). The final procedural rule will be issued before the MO rule is promulgated. If there are significant changes in the final procedural rule, EPA may allow a short period of supplementary comment on the MO proposal.

#### *F. Exemption Procedures*

Within 30 days after the effective date of the final rule, each MO manufacturer or group of MO manufacturers 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. As explained above, study plans must be submitted 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 exemptions will not be granted and will give them an opportunity to submit study plans in compliance with this rule.

Processors of MO 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, submit study plans and 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 the submission of equivalence data as a condition for exemption from the proposed testing. EPA is interested in evaluating the effects of MO and has specified in Unit C of this Preamble a relatively pure substance for testing. 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, EPA may allow a short period of supplementary comment on the MO proposal.

#### *G. Reporting Requirements*

EPA is proposing that all data be reported in accordance with the EPA Good Laboratory Practice (GLP) Standards in 40 CFR Part 792. EPA has reviewed public comments on the proposed GLP Standards and will soon publish final GLP standards.

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) 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).

The publication of the notice in the Federal Register announcing the receipt of the mutagenicity data on MO will start the deferred portion of the rule if the results of certain studies indicate that MO is mutagenic in those test systems. Persons subject to the rule will follow procedures outlined in this section for submission of study plans for this testing within the allowed time after publication of the Notice.

#### *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 or the submission of invalid data would be a violation of section 15 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 this rule. 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 Good Laboratory Practice 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 per day for each violation. Each day of operation in violation may constitute 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. Sections 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. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

#### *I. Issues*

EPA is not proposing teratogenic testing of MO because the Agency has decided it cannot make a finding of unreasonable risk due to teratogenic effects based solely on MO's chemical reactivity as an alkylator. There are no

test data indicating that MO is likely to be a teratogen. Although some chemicals which are known as alkylators are also teratogenic, chemical alkylation as a potential cause of teratogenic effects is not as well substantiated as the link between alkylating ability, reactivity with DNA, and either mutagenic or carcinogenic effects. The Agency does not believe that alkylating ability alone is a sufficient basis to support a finding of potential unreasonable risk of teratogenic effects. The Agency invites comments on this approach.

EPA is not proposing epidemiology for MO because an end-point has not been identified which could be the basis for such a study. The report by Ito on certain hematologic effects found in a pilot study of ten industrial workers correlated with blood changes in animals tested is not definitive enough to permit selection of an end-point, and in the absence of other studies the Agency cannot justify epidemiology. It is believed that the proposed subchronic testing in animals will be sufficient to define chronic health effects. EPA solicits comment on this choice of tests.

EPA is proposing that oncogenicity testing will be recommended only after the results of mutagenicity testing are evaluated. The tests which trigger a two year oncogenicity bioassay are listed in the proposed rule, and the combined schemes for chromosomal aberrations and oncogenicity and for gene mutation and oncogenicity are presented in detail in the MO support document. EPA solicits comments on this approach.

#### *III. 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 analysis 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, indicated no significant adverse economic impact exists and therefore Level II analysis was not needed for MO.

For a more complete and thorough discussion of the methodology used to conduct economic analyses of this test rule, see *Economic Impact Analysis of Proposed Test Rule for Mesityl Oxide*. For purposes of making the economic analysis, uses of the derivatives MIBK and MIBC were also taken into consideration along with end product use of MO, because demand for these

would affect production demands for MO.

Total testing costs for the proposed rule for MO are estimated to range from \$81,100 to \$260,800 if an oncogenicity test is not conducted, and \$448,100 to \$1,362,800 if an oncogenicity test is conducted. The annualized cost range \$118,510 to \$354,330 per year based upon the requirement for all tests in the proposed Notice being completed.

The potential for adverse economic effects due to this test rule is small. While certain aspects of the MO industry—such as the decline in demand for MO as an end-product—indicate that there is some potential for economic impact due to a test rule, the following factors offset that small potential: (1) The annualized test costs would be at most 0.08–0.19 cents per pound, or between 0.11 and 0.35 percent of the price per pound. (2) The close production linkage between acetone, MO, MIBK, and MIBC tends to decouple MO decisions from relatively small changes in cost. (3) Use of MO as an intermediate in MIBK production is expected to grow approximately one to two percent per year.

#### *IV. 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 20 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.

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.

#### V. Environmental 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 8, 1979 (44 FR 64174).

#### VI. 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 September 9, 1983, in Washington. This meeting is scheduled after the time 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 TSCA Assistance Office (TAO). Toll Free: (800-424-6065). 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 TAO by August 12, 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 TSCA 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.

Should a meeting be held, 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 be part of EPA's record for this rulemaking.

#### VII. Public Record

EPA has established a public record for this rulemaking (docket number OPTS-42030) 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 MO.
  - (b) Notice containing the ITC designation of MO to the Priority List [44 FR 31865].
  - (c) Notices relating to EPA's health effects test guidelines and TSCA Good Laboratory Practice standards [44 FR 27334 and 44 FR 44054].
  - (d) Notice of proposed rule on exemption policy and procedures.
  - (e) Notice of Proposed Rulemaking on reimbursement policy and procedures.
- (2) Support Documents consisting of:
  - (a) MO support document.
  - (b) Economic analysis support document.
  - (3) Minutes of informal meetings.
  - (4) Communications before proposal consisting of:
    - (a) Written public and intra-agency or interagency memoranda and comments.
    - (b) Telephone conversations.
    - (c) Meetings.
    - (d) Reports—published and unpublished factual materials, including contractors' reports.

#### VIII. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. According to Section 1. Definition "(b) 'Major rule' means any regulation that is likely to result in: (1) An annual effect on the economy of \$100 million or more; (2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets." 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 actual annual cost of all the testing proposed for MO is \$118,510-354,330, or less than \$1 million 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 (less than 0.4 percent a year) for this chemical even if all test costs were passed on. Finally, taking into account the nature of the market for this substance, 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. Any comments received from OMB are included in the Public Record for this rulemaking.

#### IX. 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 processors will not perform testing themselves, or participate in the organization of the testing effort.
2. Small processors will experience only very minor costs in securing exemption from testing requirements.
3. Small processors are unlikely to be affected by reimbursement requirements.
4. There are no small manufacturers of this chemical.

#### X. 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 forth 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.

#### List of Subjects in 40 CFR Part 793

Testing, Environmental protection, Hazardous material, Chemicals.