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**Office of Pesticides and Toxic  
Substances**

**40 CFR Part 799**

**[OPTS-42012C; FRL-2815-2]**

**Toxic Substances; Diethylenetriamine  
(DETA); Proposed Test Standards**

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

**ACTION:** Proposed rule.

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**SUMMARY:** EPA has issued a final rule under section 4(a) of the Toxic Substances Control Act (TSCA) requiring that manufacturers and processors of diethylenetriamine (DETA; CAS No. 111-40-0), test this chemical for oral subchronic (90-day) toxicity, dermal absorption, chemical fate, and mutagenicity (both gene mutation and chromosomal aberration). The Agency is now proposing that the study plans and schedules for these tests submitted by an industry consortium be adopted, with certain revisions, as the test standards and reporting deadlines for DETA under this test rule.

**DATE:** Submit written comments on or before May 27, 1986.

**ADDRESS:** Submit written comments, identified by the document control number (OETS-42012C), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E-108, 401 M Street 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, Room E-543, 401 M Street SW., Washington, D.C. 20460. Toll free: (800-424-9065); In Washington, D.C.: (554-1404). Outside the U.S.A.: (Operator-202-554-1404).

**SUPPLEMENTARY INFORMATION:** In the Federal Register of May 23, 1985 (50 FR 21398), EPA issued a final rule under section 4(a) of TSCA to require testing of DETA for oral subchronic (90-day) toxicity, dermal absorption, chemical fate, and mutagenicity (both gene mutation and chromosomal aberration). The Agency is now proposing that the industry-submitted study plans and schedules be adopted, with certain revisions, as the test standards and reporting deadlines for the required testing.

### I. Background

Diethylenetriamine (DETA, CAS No. 111-40-0) was designated by the Interagency Testing Committee (ITC) for priority testing consideration (46 FR 28139; May 22, 1981). EPA issued a proposed rule, published in the Federal Register of April 28, 1982 (47 FR 26386) in response to the testing recommendations by the ITC on DETA.

EPA promulgated, under two-phase rulemaking, a final Phase I rule requiring testing of DETA (except for chronic oncogenicity bioassay testing) on May 23, 1985 (50 FR 21398), and, on the same day, proposed, under single-phase rulemaking, that DETA be tested in chronic oncogenicity bioassays, if this substance exhibited positive results in certain required mutagenicity tests (50 FR 21413). For a detailed discussion of EPA's findings and testing requirements for all tests, except chronic oncogenicity bioassay testing, 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.

On August 6, 1985 (Refs. 1 through 3), three U.S. manufacturers of DETA notified EPA of their intent to sponsor the testing required in the final Phase I test rule and submitted proposed study plans for all required testing, except for the following mutagenicity tests, on September 6, 1985: the dominant lethal assay, the heritable translocation assay, and the mouse specific locus assay. Also, on August 6, 1985, member companies of the Diethylenetriamine Producers/Importers Alliance (DPIA), a consortium composed of these three manufacturers of DETA and other current manufacturers or importers and one future manufacturer, requested an extension of the deadline for the submission of study plans for these three mutagenicity assays, which was denied by the Agency because adequate time was available to the DPIA for the preparation of these study plans before the legal deadline for October 7, 1985. On September 19, 1985, a meeting was held between EPA and DPIA representatives at which the study plans which had been submitted to the Agency on September 6, 1985, were discussed.

On September 30, 1985, legal counsel for the DPIA requested, on its behalf, an extension of the deadline for the submission of the study plan for the mouse specific locus assay, stating that the study plan could not be developed because the DPIA had been unable to identify a laboratory which would agree to perform the test in accordance with EPA's Good Laboratory Practice Standards (GLP's). EPA denied this request for an extension of the deadline for the submission of the study plan for the mouse specific locus assay because:

(1) The legal deadline for such requests (September 6, 1985) had passed; (2) as stated in 40 CFR 790.30(c)(2), the identification of a testing facility and personnel is not required in study plans if the information is not available at the time of the study plan submission, but must be submitted before the initiation of testing; and (3) adequate time existed for the submission of this study plan before the legal deadline, using the TSCA Health Effects Test Guideline for this assay as guidance.

EPA is aware that the DPIA has been unable to identify a qualified testing facility which has had previous experience with performing the Mouse Specific Locus Test for Visible Markers and is capable of performing this test in a manner consistent with test rule requirements. However, this situation may well have changed by the time such testing becomes required for DETA, since testing facilities may decide to offer this test as they become familiar with the fact that the Mouse Specific Locus Test for Visible Markers is included in the tiered sequence of testing for gene mutation which the Agency routinely requires in TSCA section 4(a) test rules for chemical substances requiring testing for their potential to elicit gene mutations. In addition, the Agency is investigating what actions the EPA might take to aid in insuring that qualified testing facilities are available to perform this test for chemical substances subject to a test rule requirement for this assay. The Agency will reexamine the question of the availability of qualified testing facilities which are available to perform this test for DETA during the public program review of all of the mutagenicity data for DETA which, as described in the final Phase I test rule for DETA (50 FR 21398; May 23, 1985), will precede the initiation of the testing of DETA in the mouse specific locus test. Should the Agency conclude that no qualified testing facility is available at that time to perform this testing, EPA may propose to rescind this testing requirement for DETA and after consideration of public comments on the proposed amendment to the test rule, issue a final decision whether to rescind this test rule requirement.

On October 7, 1985, the Agency received from the DPIA study plans for all of the tests required for DETA in the final Phase I test rule for this substance (50 FR 21398; May 23, 1985). After review and evaluation of these study plans, the Agency requested on November 7, 1985, that the DPIA make certain revisions. On December 2, 1985, the Agency received from the DPIA a complete set of all of the study plans for

all of the testing required for DETA. These study plans either contained revisions in response to the Agency's request or justifications, contained in cover letters, as to why certain suggested revisions were not made.

After review of the study plans for DETA submitted by the DPIA on December 2, 1985, the EPA concluded that certain revisions were still necessary to transform these plans into acceptable test standards for the testing required for DETA. These revisions were incorporated into a document entitled "Study Plans for Diethylenetriamine (DETA): Confirmation of EPA's Receipt, Evaluation, and Revision," which, together with the attached submitted study plans, shall be referred to as the EPA-approved modified study plans for DETA (Ref. 4).

EPA has modified the study plan contained in Ref. 4 identified as "Testing to Assess Potential Environmental Production of *N*-Nitroso Adducts of Diethylenetriamine" by deleting Alternative 1 on page 2 of that study plan and utilizing Alternative 2. Alternative 1 proposes that DETA be tested in sewage first and, if no nitrosamine derivatives of DETA are detected in this environmental sample, then testing in lake water and soil would not be conducted. Alternative 2 proposes that DETA be tested in sewage first and subsequently in lake water and soil, regardless of the test results obtained in sewage. The Agency believes that testing in all three environmental samples is necessary, and the final Phase I test rule for DETA (50 FR 21398; May 23, 1985) clearly requires that testing shall be conducted in all three environmental samples [40 CFR 799.1575(d)(1)]. Only Alternative 2 of this study plan fulfills this testing requirement for DETA.

EPA has also modified the study plan contained in Ref. 4 identified as the "Mouse Specific Locus Test for Visible Markers" by changing the last sentence in section D.1. on page 4 of the study plan to read: A laboratory with no prior experience with the test shall provide negative and positive control validation data conforming to the requirements of 40 CFR 798.5200(d)(4)(i), prior to conducting the assay. This revision is necessary to insure that the study plan conforms to the TSCA Health Effects Test Guidelines for this test (40 CFR 798.5200).

In the Agency's request to the DPIA (of November 7, 1985) for the revisions of study plans, EPA suggested that the time periods allowed in several of these study plans for the completion of testing be shortened. The Agency based these

suggestions upon previous regulatory experience with these tests within EPA's Office of Pesticides and Toxic Substances and discussions with commercial testing laboratories. Cover letters attached to the EPA-approved modified study plans for DETA (Ref. 4) explain that all of the testing, except for the Mouse Specific Locus Test for Visible Markers, will be conducted within the laboratories of member companies of the DPIA, that these laboratories are fully utilized for testing purposes at all times, that it would be quite difficult for these laboratories to arrange testing schedules around an estimated promulgation date for the final Phase II test rule for DETA, and that the time periods allowed in the submitted study plans allowed about 2 months for the testing laboratories to reschedule their activities as a result of the final Phase II test rule for DETA. With respect to the EPA-approved modified study plan for the Mouse Specific Locus Test for Visible Markers (Ref. 4), an attached cover letter asserts that the time period allowed in this study plan for the completion of testing was selected following consultation with various commercial testing laboratories; however, the letter also states that no qualified testing facility could be identified which has had previous experience in performing this test and is capable of conducting the test in a manner consistent with the test rule requirements.

The Agency has carefully considered the comments contained in cover letters attached to the EPA-approved modified study plans contained in Ref. 4, and is proposing reporting deadlines for the submission of final reports for all of the testing required for DETA which are essentially in agreement with the schedules proposed by the DPIA. However, for all testing required for DETA, the Agency is proposing that brief interim progress reports be submitted to EPA at consecutive 3-month intervals following the date on which each test becomes mandatory until the submission of the final report to EPA. The Agency believes that these interim progress reports are necessary to keep EPA informed of the current status of the testing required for DETA and to alert the Agency of any difficulties which the testing facilities may encounter during the course of testing. In addition, the Agency wishes to review the selection of dosage levels based upon preliminary data prior to the initiation of certain studies (e.g., the rodent heritable translocation assay, the mouse specific locus assay, and the mammalian subchronic toxicity study), and the required submission of interim

3-month reports will aid the EPA in this review function.

The Agency is now proposing that the EPA-approved modified study plans for DETA (and the reporting deadlines contained within them) be adopted as the test standards and reporting requirements for the required testing of DETA.

## II. Proposed Test Standards

A consortium of manufacturers (including importers) and a future manufacturer of DETA, known as the DPIA, including Union Carbide Corporation, Dow Chemical Company, Texaco Chemical Company, Borel Chemicals, Inc., AZS Corporation, BASF Wyandotte Corporation, and Air Products and Chemicals, Inc., has notified of EPA of their agreement to sponsor the testing required in the final Phase I rule for DETA in 40 CFR 799.1575. The DPIA has submitted proposed study plans for the required testing, which, after evaluation, the EPA has revised, resulting in the EPA-approved modified study plans for DETA (Ref. 4). The DPIA proposes to conduct the following studies: Fourteen-Day (Range-Finding) Dietary Toxicity Study with Diethylenetriamine in Albino Rats, Ninety-Day (Subchronic) Dietary Toxicity Study with Diethylenetriamine in Albino Rats, Absorption/Elimination Study of Diethylenetriamine following Dermal Application in Male and Female Fischer-344 Rats, Testing to Assess the Potential Environmental Production of *N*-Nitroso Adducts of Diethylenetriamine, Sex-linked Recessive Lethal Gene Mutation Test in *Drosophila melanogaster*, and an Evaluation of Diethylenetriamine in an *In Vitro* Chromosomal Aberration Assay Utilizing Chinese Hamster Ovary Cells. In addition, should the appropriate lower-tier mutagenicity tests yield certain results for DETA, the following mutagenicity tests will also be performed: Mouse Specific Locus Test for Visible Markers, Evaluation of Diethylenetriamine in the Mouse Bone Marrow Micronucleus Test, Dominant Lethal Assay of Diethylenetriamine in CD Rats, and Heritable Translocation Assay of Diethylenetriamine in CD-1 Mice.

The EPA-approved modified study plans for all of these tests (Ref. 4) are available for inspection in the public docket for this proposed Phase II test rule, and the Agency is now proposing these plans as the test standards for conducting the testing of DETA required under 40 CFR 799.1575. All of the testing conducted according to the EPA-approved modified study plans for

DETA will be conducted in accordance with EPA's TSCA Good Laboratory Practice Standards as set forth in 40 CFR Part 792, and the EPA-approved modified health effects study plans all conform to the appropriate TSCA Health Effects Test Guidelines (40 CFR Part 798) or contain justified deviations from the appropriate guidelines.

### III. Reporting Requirements

EPA is proposing the schedules contained in the EPA-approved modified study plans for DETA (Ref. 4) as the reporting requirements. These reporting requirements are summarized as follows:

REPORTING DEADLINES FOR DETA

Test	Reporting deadline for final report (months after the effective date of final phase II rule)	Number of interim (3-month) reports required
Sex-linked recessive lethal test in <i>Drosophila</i>	14	3
Mouse specific locus assay	62 <sup>a</sup> (48)	15
<i>In vitro</i> cytogenetics test	6	1
<i>In vivo</i> cytogenetics test	14 <sup>a</sup> (8)	1
Dominant lethal test	20 <sup>a</sup> (6)	1
Heritable trans-location assay	38 <sup>a</sup> (18)	5
90-day subchronic toxicity test	15	4
Dermal absorption test	20	5
Chemical fate test	18	5

<sup>a</sup> Figure includes the time period required for previous required testing.

<sup>b</sup> Figure in parenthesis indicates the time period allowed for completion of the test itself, not including the time periods for previous required testing.

### IV. Issues for Comment

The Agency invites comments on the EPA-approved modified study plans for DETA; copies of these study plans are included in the public record for this rule. EPA also invites comment on EPA's proposed schedules for the required testing.

### V. Public Record

EPA has established a public record for this rulemaking (docket number OPTS-42012C). 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.

This record now includes the following information:

#### A. Supporting Documentation

- (1) Final Phase I rule on diethylenetriamine.
- (2) Contact reports of telephone conversations.
- (3) Letters and memoranda related to this rulemaking.

(4) EPA and DPLA summaries of a meeting held on September 19, 1985, to discuss study plans for the required testing of DETA.

### B. References

- (1) Union Carbide Corporation. Letter from J. Cole to TSCA Public Information Office. USEPA. August 2, 1985.
- (2) Dow Chemical Company. Letter from W. Cornelius to TSCA Public Information Office. USEPA. July 29, 1985.
- (3) Texaco Chemical Company. Letter from F. Bentley to TSCA Public Information Office. USEPA. August 5, 1985.
- (4) Diethylenetriamine Producers/Importers Alliance (DPLA). Letter from A. Rautio (and attached study plans and associated cover letters for diethylenetriamine) to G. Timm. USEPA. November 27, 1985. (And attached Confirmation of EPA's Receipt, Evaluation, and Revision. February 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 required for DETA is discussed in the Phase I test rule (50 FR 21398; May 23, 1985).

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, together with any EPA response to these comments, 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 is not a significant number of small businesses manufacturing DETA.
2. Small manufacturers and small processors of DETA are not expected to perform testing themselves or to participate in the organization of the testing efforts.
3. Small manufacturers and small processors of DETA will experience only minor costs, if any, in securing exemption for testing requirements.

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

### C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned the OMB control number 2070-0033. Submit comments on these requirements to the Office of Information and Regulatory Affairs: OMB; 726 Jackson Place, NW.; Washington, D.C. 20503, marked "Attention: Desk Officer for EPA." The final rule 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, Recordkeeping and reporting requirements.

Dated: April 3, 1986.

J. A. Moors,

Assistant Administrator for Pesticides and Toxic Substances.

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

### PART 799—[AMENDED]

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

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

2. By amending § 799.1575 by revising paragraphs (c)(1)(ii), (2)(ii), (3)(ii), and (4)(ii), and (d); adding paragraphs (c)(1)(iii), (2)(iii), (3)(iii), and (4)(iii); and removing paragraph (e) to read as follows:

#### § 799.1575 Diethylenetriamine (DETA).

(c) \* \* \*

(1) \* \* \*

(ii) *Test standards.* The testing shall be conducted in accordance with the following EPA-approved modified study plans (February 10, 1986) developed by the Diethylenetriamine Producers/Importers Alliance (DPLA): "Sex-linked recessive lethal test in *Drosophila melanogaster*," and "Mouse specific locus test for visible markers." These EPA-approved modified study plans are available for inspection in EPA's OPTS Reading Room, Rm. E-107, 401 M St., SW., Washington, DC 20460; copies of these study plans are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* (A) The sex-linked recessive lethal test of DETA

in *Drosophila melanogaster* shall be completed and a final report submitted to the Agency within 14 months from the effective date of the final Phase II rule. Three interim progress reports shall be submitted at 3-month intervals.

(B) If required pursuant to paragraph (c)(1)(i)(B) of this section, the mouse specific locus test of DETA for visible markers shall be completed and a final report submitted to the Agency within 62 months from the effective date of the final Phase II rule. Fifteen interim progress reports shall be submitted at 3-month intervals, the first of which is due within 17 months of the effective date of the final Phase II rule.

(2) \* \* \*

(ii) *Test standards.* The testing shall be conducted in accordance with the following EPA-approved modified study plans (February 10, 1986) developed by the Diethylenetriamine Producers/Importers Alliance (DPIA): "In vitro cytogenetics test," "In vivo cytogenetics test," "Dominant lethal assay of diethylenetriamine in CD rats," and "Heritable translocation assay of diethylenetriamine in CD-1 mice." These EPA-approved modified study plans are available for inspection in EPA's OPTS Reading Room, Rm. E-107, 401 M Street SW., Washington, DC 20460; copies of these plans are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* (A) The *in vitro* cytogenetics testing of DETA shall be completed and a final report submitted to the Agency within 6 months of the effective date of the final Phase II rule. One interim progress report shall be submitted within 3 months of the final rule's effective date.

(B) If required pursuant to paragraph (c)(2)(i)(B) of this section, the *in vivo* cytogenetics testing of DETA shall be completed and final report submitted to the Agency within 14 months of the effective date of the final Phase II rule. One interim progress report shall be submitted within 9 months of the final rule's effective date.

(C) If required pursuant to paragraph (c)(2)(i)(C) of this section, the dominant lethal testing of DETA shall be completed and a final report submitted to the Agency within 20 months of the final Phase II rule. One interim progress report shall be submitted within 17 months of the final rule's effective date.

(D) If required pursuant to paragraph (c)(2)(i)(D) of this section, the heritable translocation testing of DETA shall be completed and a final report submitted to the Agency within 36 months of the effective date of the final Phase II rule. Five interim progress reports shall be submitted at 3-month intervals, the first

of which is due within 23 months of the effective date of the final Phase II rule.

(3) \* \* \*

(ii) *Test standards.* The testing shall be conducted in accordance with the following EPA-approved modified study plan (February 10, 1986) developed by the Diethylenetriamine Producers/Importers Alliance (DPIA): "Ninety-day (subchronic) dietary toxicity study with diethylenetriamine in albino rats." This EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. E-107, 401 Street SW., Washington, D.C. 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The testing shall be completed and a final report submitted to the Agency within 15 months of the effective date of the final Phase II rule. Four interim progress reports shall be submitted at 3-month intervals.

(4) \* \* \*

(ii) *Test standard.* The testing shall be conducted in accordance with the following EPA-approved modified study plan (February 10, 1986) developed by the Diethylenetriamine Producers/Importers Alliance (DPIA): "Dermal absorption." This EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. E-107, 401 M St., SW., Washington, D.C. 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The testing shall be completed and the final report submitted to the Agency within 20 months of the effective date of the final Phase II rule. Five interim progress reports shall be submitted at 3-month intervals.

(d) *Chemical fate testing—(1) Required testing.* Testing to assess N-nitrosamine formation, resulting from aerobic biological and/or chemical transformation, shall be conducted with DETA using environmental samples of lake water, sewage, and soil.

(2) *Test standard.* The testing shall be conducted in accordance with the following EPA-approved modified study plan (February 10, 1986) developed by the Diethylenetriamine Producers/Importers Alliance (DPIA): "Chemical fate." This EPA-modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. E-107, 401 M St., SW., Washington, D.C. 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(3) *Reporting requirements.* The testing shall be completed and a final report submitted to the Agency within

18 months of the effective date of the final Phase II rule. Five interim progress reports shall be submitted at 3-month intervals.

(e) [Removed]

(Information collection requirements approved by the Office of Management and Budget under control number 2070-0033).

[FR Doc. 86-8007 Filed 4-9-86; 8:45 am]

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