

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42012E; FRL-3609-3]

Diethylenetriamine (DETA); Proposed Amendments to Test Rule**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: EPA is proposing to amend the test rule for DETA in 40 CFR 799.1575 by extending the deadline for submission of the final report on the chemical fate testing and by rescinding the requirement for dermal absorption testing. The proposed extension would require submission of the final report twelve months after the final rule incorporating this amendment is published in the Federal Register.

DATE: Submit written comments on or before July 28, 1989.

ADDRESS: Written comments, in triplicate, identified by docket number [OPTS-42012E], should be submitted to: TSCA Public Docket Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-G004, 401 M Street SW., Washington, DC 20460

A public version of the administrative record supporting this action 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: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. EB-44, 401 M Street SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA is proposing under TSCA section 4(a) to modify the chemical fate and dermal absorption testing requirements for DETA in 40 CFR 799.1575.

I. Introduction**A. Regulatory History**

Section 799.1575 of 40 CFR requires the testing of DETA for oral subchronic toxicity, dermal absorption (in the same animal species used for the subchronic testing), mutagenicity (tiered sequences of tests for detecting chromosomal aberrations and gene mutations), and chemical fate testing (for the detection of possible chemical or biological transformations of DETA to *N*-nitrosamines in samples of soil, lake water, and sewage sludge). The primary purpose of the dermal absorption testing of DETA was to relate potentially adverse effects which might be observed

in the required 90-day oral subchronic toxicity study to expected exposure by the dermal route.

EPA has received and evaluated the final reports resulting from all of the testing required for DETA except for chemical fate and dermal absorption. On two occasions, pursuant to 40 CFR 790.55, Dow Chemical Company (the test sponsor for both of these tests), requested that EPA extend the reporting requirement deadlines for the submission of the final reports for these two tests because it was unable to obtain the ¹⁴C-radiolabelled DETA necessary for the conduct of these studies from reputable contract laboratories. In a letter of October 22, 1987 (Ref. 1), the test sponsor requested a 4-month extension of the reporting deadlines for these two tests. In its letter of February 15, 1988, (Ref. 3), the sponsor requested an additional 2-month extension. Both these requests were granted by EPA (Refs. 2 and 4).

In letters dated September 18, 1988 (Ref. 5), and September 29, 1988 (Ref. 6), the test sponsor requested an additional 1-year extension of the deadlines for the final reports for these two tests, due to continuing difficulties in obtaining the required radiolabelled DETA. The sponsor provided supplemental information to justify the request. Because the test sponsor has already received extensions totalling 6 months, any further extensions of these deadlines must be considered, pursuant to 40 CFR 790.55 (b)(3) and (4)(iv), to significantly change the schedule for completing testing, and require notice and public comment.

B. Proposed Modifications

EPA has carefully evaluated the data contained in references 1, 3, 5, and 6, and has concluded that the test sponsor's difficulties in obtaining the ¹⁴C-radiolabelled DETA necessary to conduct the chemical fate and dermal absorption testing of DETA warranted the previous extensions of the deadlines for the final reports for these two tests already granted by EPA, and continues to warrant a further extension in the deadline for the chemical fate testing of DETA. EPA is proposing that the deadline for the chemical fate testing of DETA be extended by 12 months from the effective date of the final rule resulting from this proposal. EPA believes that this 12-month extension will provide the test sponsor adequate time to obtain the radiolabelled test substance, and conduct the testing.

EPA is proposing to rescind the requirement for dermal absorption testing of DETA for the following reasons: (1) The dermal absorption

testing of DETA was required to relate potential adverse effects which might be observed in the required 90-day dietary subchronic toxicity study to the expected dermal route of human exposure; (2) EPA's evaluation of the 90-day dietary subchronic toxicity study (Ref. 8) indicates that no significant toxic effects were observed in this study; and (3) the available acute toxicity data indicate that DETA would be expected to be about equally or only slightly more toxic following administration by the dermal as compared with the oral route of administration (Ref. 9).

II. Rulemaking Record

EPA has established a record for this rulemaking (Docket Number OPTS-42012E). This record contains the basic information considered by EPA in developing this proposal and appropriate Federal Register notices.

This record includes:

A. Supporting Documentation

(1) Final Phase II rule on diethylenetriamine (53 FR 3230; February 3, 1987).

(2) Contact reports of telephone conversations.

B. References

(1) The Dow Chemical Company (Dow). Letter to the Director, Office of Compliance Monitoring (OCM), Office of Pesticides and Toxic Substances (OPTS), U.S. Environmental Protection Agency (EPA), (October 22, 1987).

(2) OPTS, EPA. Letter to John Gray, Dow. (December 18, 1987).

(3) Dow. Letter to the Director, OCM, OPTS, EPA. (February 15, 1988).

(4) OPTS, EPA. Letter to John Gray, Dow. (April 5, 1988).

(5) Dow. Letter to the Director, OCM, OPTS, EPA. (September 18, 1988).

(6) Dow. Letter to the Director, OCM, OPTS, EPA. (September 29, 1988).

(7) Existing Chemical Assessment Division, EPA. Letter to John Gray, Dow. (October 24, 1988).

(8) Health and Environmental Review Division (HERD), EPA. Memorandum to Richard Troast, Test Rules Development Branch (TRDB), EPA. (August 4, 1988).

(9) HERD, EPA. Memorandum to Richard Troast, TRDB, EPA. (October 21, 1988).

The record for this rulemaking is available for inspection in the OPTS Reading Room, G-004, NE Mall, 401 M Street SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday except legal holidays. EPA will supplement the record periodically with additional relevant information.

III. Other Regulatory Requirements**A. Executive Order 12291**

Under Executive Order 12291, EPA judged that the final Phase II test rule for DETA was not "major" and therefore was not subject to the requirement of a Regulatory Impact Analysis. The proposed modifications to the rule do not alter this determination.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA responses to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq., Pub. L. 96-354, September 19, 1980), EPA certified that the final Phase II rule for DETA would not have a significant impact on a substantial number of small businesses. The proposed modifications do not alter this certification.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et seq. and have been assigned OMB control number 2070-0693.

Public reporting burden for the collection of information is expected to be altered by this modification by adding an estimated eight hours of time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information in preparing an additional semiannual progress report.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 799

Chemicals, Environmental protection, Hazardous substances, Testing, Laboratories, Recordkeeping and reporting requirements.

Dated: June 19, 1989.

Victor J. Kizza,

Acting 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 would continue to read as follows:

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

2. In § 799.1575 by removing paragraph (c)(4) and revising paragraph (d)(3) and (f) to read as follows:

§ 799.1575 Diethylenetriamine (DETA).

(d) . . .

(3) *Reporting requirements.* The testing shall be completed and a final report submitted to EPA within 12 months of (the effective date of the final rule granting a 12-month extension of the deadline for the final report).

(f) *Effective dates.* The effective date of 40 CFR 799.1575, final Phase II rule for DETA, is March 19, 1987, except for paragraph (3)(3) which is effective 44 days after publication in the Federal Register of the final rule granting a 12-month extension of the deadline for the final report).

[FR Doc. 89-15272 Filed 6-27-89; 8:45 am]

BILLING CODE 6550-01-02