

**40 CFR Part 799**

[OPTS-42028D; FRL-3265-9]

**Propylene Oxide: Final Test Standards and Reporting Requirements**

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

**ACTION:** Final rule.

**SUMMARY:** Under section 4 of the Toxic Substances Control Act (TSCA), this final rule specifies test standards and reporting requirements to be used for the testing required of manufacturers and processors of propylene oxide (CAS No. 75-56-9). The Agency has adopted industry-submitted study plans, as modified by EPA (EPA-approved study plans) as test standards for conducting the inhalation developmental toxicity testing for propylene oxide under 40 CFR 799.3450.

**DATES:** In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ("daylight" or "standard" as appropriate) time on October 7, 1987. This rule shall become effective on November 6, 1987.

**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, DC 20460, (202-554-1404).

**SUPPLEMENTARY INFORMATION:** EPA is promulgating a final rule under section 4(a) of TSCA specifying the test standards and reporting requirements for inhalation developmental toxicity testing of propylene oxide.

**I. Background**

In the Federal Register of November 27, 1985 (50 FR 48762), EPA issued a final Phase I rule pursuant to TSCA section 4 that establishes testing requirements for manufacturers and processors of propylene oxide. This Phase I rule requires inhalation developmental toxicity testing for propylene oxide.

At the same time, EPA proposed a relevant TSCA test guideline as the test standard (50 FR 48803; November 27, 1985). In addition, EPA proposed that the data from the required study be submitted within a certain time period, the time period serving as the data submission deadline required by TSCA section 4(b)(1). The reasons for this change in the test rule development process for propylene oxide are discussed in Unit II of the preamble to the proposed test standards (50 FR 48803).

As discussed in the preamble to the interim final Test Rule Development and Exemption Procedures, 40 CFR Part 790 (50 FR 20652; May 17, 1985), industry and other commenters may suggest an alternative methodology or modifications to the OTS test guideline, i.e., the proposed test standard, during the public comment period. The final test standard would be either the OTS test guideline or other suitable guideline, a modified version of this guideline, the alternative methodology submitted by commenters, or a modified version of the alternative methodology.

On February 6, 1986, ARCO Chemical Company (ARCO) notified EPA of its intent to conduct the testing required in the Phase I test rule for propylene oxide (Ref. 1). Exemption applications were received from Dow Chemical Company (Dow) (Ref. 2) and two processors, Exxon Chemical Americans (Ref. 3) and Aldrich Chemical Co. (Ref. 4). On June 26, 1986, ARCO submitted two draft study plans containing two protocols (Ref. 5) to EPA for review and approval. EPA determined that these protocols generally conform to the Health Effects Test Guideline set forth in 40 CFR 798.4350. EPA notified ARCO on August 1, 1986 (Ref. 6) that, with certain specified clarifications, the Agency found the protocols to be appropriate and acceptable for inhalation developmental toxicity testing for propylene oxide. ARCO submitted two final study plans containing two protocols to EPA on October 28, 1986 (Ref. 7).

EPA has found the industry-submitted final study plans (Ref. 7) as modified by EPA (Ref. 6) to be acceptable for assessing the developmental toxicity of propylene oxide (Ref. 8). As a result, EPA is promulgating them, along with reporting requirements, as Phase II test standards for the testing of propylene oxide under 40 CFR 799.3450.

**II. Proposed Phase II Test Rule**

**A. Test Standards**

The Phase I rule specifies that propylene oxide be tested for inhalation developmental toxicity. The Agency's proposed Phase II rule specified that testing of propylene oxide be conducted using as the test standard the TSCA guideline for inhalation developmental toxicity testing, 40 CFR 798.4350.

**B. Reporting Requirements**

As specified in 40 CFR 799.10, all data developed under this rule would be reported in accordance with its TSCA Good Laboratory Practice (GLP)

Standards which appear at 40 CFR Part 792.

EPA is required by section 4(b)(1)(C) of TSCA to specify the time period during which persons subject to a test rule must submit test data. The Agency proposed that: (1) The inhalation developmental toxicity test be completed and the final results submitted to the Agency within 12 months of the effective date of the final rule, and (2) the interim progress reports be provided quarterly.

### III. Response To Public Comments

The Agency received comments from ARCO and Dow (Refs. 5 and 9). A public meeting was not requested. The major issues identified for the proposed test standard and reporting requirements are discussed in Units III.A. and B.

#### A. Developmental Toxicity Testing

Dow (Ref. 9) commented that, while the Phase II proposed rule specified that the rat be used as the mammalian test species, the preamble to the final Phase I rule suggested that a rat strain other than Sprague-Dawley be selected for the conduct of the study (see 50 FR 48764; November 27, 1985). Dow does not believe that compelling evidence exists to require the selection of an alternate strain, and therefore suggests that selection of an appropriate rat strain be done by the laboratory conducting the test. Dow also commented that EPA had not adequately considered the availability of facilities and personnel to perform the inhalation developmental toxicity testing required under the Phase I rule.

EPA believes that this is no longer a concern because ARCO has agreed to sponsor the developmental toxicity study and has informed EPA that the study can be conducted at the International Research and Development Corporation using the Fisher 344 rat. EPA finds this acceptable.

ARCO did not submit comments on the proposed test standards to EPA during the comment period. Subsequent to the comment period, however, ARCO submitted two draft study plans containing two protocols to EPA for review and approval on June 20, 1986 (Ref. 5). EPA notified ARCO on August 1, 1986, that with certain specified clarifications (Ref. 6), the Agency found the protocols to be appropriate and acceptable for developmental toxicity testing of propylene oxide. ARCO submitted copies of the final study plans containing two protocols on October 28, 1986 (Ref. 7). The final study plans (Ref. 7) along with the EPA clarifications sent to ARCO (Ref. 6) are the EPA-approved

study plans for propylene oxide (Ref. 8) and are promulgated in this final rule as the test standards for the testing of propylene oxide.

#### B. Reporting Requirements

Dow (Ref. 9) commented that while a 12-month period is sufficient to complete a teratology study, the requirement to submit the final report within 12 months of the effective date of the final Phase II rule is not justified. Instead Dow suggested that the data submission deadline be extended to 18 months from the effective date of the final rule.

EPA now generally requires that a final report be submitted within 15 months of the effective date of a final rule requiring inhalation developmental toxicity testing. However, because ARCO has already begun the required testing, EPA does not believe that it is unreasonable to require the submission of the final report no later than 12 months from the effective date of this final Phase II rule, as originally proposed.

Dow questioned the utility of the proposed requirement that progress reports be provided to EPA on a quarterly basis (Ref. 9). Dow maintains that such a reporting schedule unduly burdens those doing the study.

EPA believes that progress reports are necessary to keep EPA informed of the status of required testing and any difficulties that the testing facility may encounter during the course of testing. EPA has decided, however, that one interim progress report, submitted 6 months after this final Phase II rule is effective, will be sufficient to keep EPA apprised of such information.

### IV. Final Phase II Test Rule

#### A. Test Standards

The protocols contained in the EPA-approved study plans specify test methods and conditions for conducting both probe and definitive inhalation developmental toxicity studies in rats under this final Phase II rule. The Agency believes that the conduct of the required studies in accordance with these test standards will ensure that the resulting data are reliable and adequate. There are essentially no differences in the EPA-approved study plans and the Health Effects Test Guideline set forth in 40 CFR 796.4350.

Under the final test standards, exposure levels of 0, 300, 500, and 750 parts per million (ppm) of propylene oxide for 6 hours/day will be used for the Fisher 344 rat (days 6 through 15 of gestation) probe studies, with exposure levels for the full inhalation developmental toxicity studies based

on results of the probe studies. The EPA-approved study plans (Ref. 8) are available in the public docket for this action. The EPA-approved study plans conform to the TSCA Health Effects Test Guidelines for Inhalation Toxicity Testing, 40 CFR 796.4350.

#### B. Reporting Requirements

The Agency requires that all data developed under this rule be reported in accordance with the TSCA GLP Standards (40 CFR Part 792).

The Agency 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.

Testing was initiated by ARCO on October 27, 1986, and all results must be reported to EPA within 12 months of the effective date of the final Phase II rule. In addition, a progress report must be submitted to the Agency 6 months after the effective date of this Phase II final rule.

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).

#### C. Exemptions

Requests for exemptions from the testing requirements contained in the final TSCA section 4(a) Phase I test rule for propylene oxide (CAS No. 75-55-9) were received from a manufacturer, Dow (Ref. 2), and two processors, Exxon Chemical Americas and Aldrich Chemical Company (Refs. 3 and 4), and have been conditionally approved by the Agency. As described in the final rule for test rule development and exemption procedures (40 CFR Part 790), exemption applications are evaluated prior to the promulgation of the final Phase II test rule. Exemptions to these testing requirements are being granted to Dow and all processors on the condition that the test sponsor will successfully complete the required testing according to the test standards and data submission deadlines in this final Phase II test rule for propylene oxide. If the Agency finds it necessary to terminate conditional exemptions from the testing requirement for propylene oxide, it will notify the exemption holders to that effect and explain the reasons for the Agency's decision.

A letter of intent to test has been received for the requirements contained in the final Phase I test rule for propylene oxide from ARCO (Ref. 1). As described in EPA's final rule on data

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reimbursement (40 CFR Part 791), when the Agency promulgates a final test rule, all of the manufacturers, importers, and processors of the chemical substance or mixture subject to the rule are expected to bear jointly the cost of testing. Because the Agency has granted conditional approval of these exemption requests, persons who have been granted exemptions should contact ARCO to arrange appropriate reimbursement for a share of the cost of this testing. If a company believes that confidentiality so requires, such contact may be made through a third party.

#### D. Judicial Review

The promulgation date for the propylene oxide Phase I final rule was established as 1 p.m. eastern standard time on December 11, 1985 (50 FR 48762; November 27, 1985). To EPA's knowledge, EPA received no petitions for judicial review of that Phase I final rule. Accordingly, any petition for judicial review of this final Phase II rule will be limited to a review of the test standards and reporting requirements for propylene oxide established in this final Phase II rule.

#### E. Other Provisions

TSCA section 4 findings, required testing test substance specifications, persons required to test, enforcement provisions, and the economic analysis are presented in the final Phase I rule for propylene oxide.

#### V. Rulemaking Record

EPA has established a record for this rulemaking. (Docket Number OPTS-42028E). This record includes basic information considered by the Agency in developing this rule and appropriate Federal Register notices.

This record includes the following information:

##### A. Supporting Documentation

The supporting documentation for this rulemaking consists of the proposed and final Phase I test rules for propylene oxide (49 FR 436, January 6, 1984; 50 FR 48762, November 27, 1985) and the proposed Phase II test standards (50 FR 48808, November 27, 1985) rule and the following:

- (1) Federal Register notices pertaining to this final rule consisting of:
  - (a) Notice of interim final rule on test rule development and exemption procedures (50 FR 20652; May 17, 1985).
  - (b) Judicial Review under EPA-Administered Statutes (50 FR 7270; February 21, 1985).
  - (c) Notice of proposed rule on

revisions of TSCA guidelines (51 FR 1522; January 14, 1986).

- (2) Communications consisting of:
  - (a) Written public comments.
  - (b) Summaries of phone conversations.

(3) Chemical Testing Industry: Profile of Toxicological Testing, prepared by Development Planning and Research Associates, Inc. and ICF Incorporated for U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Washington, DC 20460 (October 1981).

#### B. References

(1) ARCO Chemical Company. Letter to TSCA Public Information Office, Office of Pesticides and Toxic Substances, Environmental Protection Agency, Washington, DC, from Joan L. McCuen, ARCO Chemical Company, Newtown Square, PA. Notice of intent to test propylene oxide (February 6, 1986).

(2) Dow Chemical Company. Letter to TSCA Public Information Office, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, from R.A. Gerardo, Dow Chemical Company, Midland, Michigan. Application for exemption from conducting testing of propylene oxide (February 7, 1986).

(3) Exxon Chemical Americas. Letter to Document Control Officer, U.S. Environmental Protection Agency, Washington, DC, from Harry L. Hunter, Jr., Exxon Chemical Americas, Houston, TX. Application for exemption from conducting testing of propylene oxide (February 14, 1986).

(4) Aldrich Chemical Company, Inc. Letter to Document Control Officer, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, from Allison W. Rusquist, Ph.D., Aldrich Chemical Company, Inc., Milwaukee, Wisconsin. Application for exemption from conducting testing of propylene oxide (January 8, 1986).

(5) ARCO Chemical Company. Letter, containing two draft study plans for testing propylene oxide, to Ralph Northrop, Test Rules Development Branch, Office of Pesticides and Toxic Substances, Environmental Protection Agency, from Joan L. McCuen, ARCO Chemical Company, Newtown Square, PA (June 28, 1986).

(6) USEPA. Letter, notifying ARCO Chemical Company that their protocols are acceptable, to Joan McCuen, ARCO Chemical Company, Newtown Square, PA, from Gary E. Timm, Test Rules Development Branch, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC (August 1, 1986).

(7) ARCO Chemical Company. Letter, containing final study plans for testing propylene oxide, to Ralph Northrop, Test Rules Development Branch, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, from Joan McCuen, ARCO Chemical Company, Newtown Square, PA (October 28, 1986).

(8) U.S. Environmental Protection Agency. Study Plans for Propylene Oxide (EPA-approved study plans, July 22, 1987).

(9) Dow Chemical Company. Letter, comments on proposed test standards and reporting requirements of propylene oxide, to Document Control Officer, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC, from Carlos M. Bowman, Ph.D., Dow Chemical Company, Midland, Michigan (January 8, 1986).

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Room NE-C604, 401 M St., SW., Washington, DC, 20460.

#### VI. Other Regulatory Requirements

##### A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The economic analysis of the testing of propylene oxide is discussed in the Phase I test rule (50 FR 48762; November 27, 1985).

This final Phase II test rule 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 (5 U.S.C. 601 *et seq.*; Pub. L. 96-354, September 18, 1980), EPA is certifying that this test rule will not have a significant impact on a substantial number of small businesses for the following reasons:

- (1) There are no small manufacturers of this chemical substance.
- (2) Small processors are not expected to perform testing themselves, or participate in the organization of the testing effort.
- (3) Small processors are unlikely to be affected by reimbursement requirements.

##### C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in the final Phase II rule under the provisions of the Paperwork Reduction Act of 1980.

44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070-0033. No public comments on these requirements were submitted to the Office of Information and Regulatory Affairs of OMB.

**List of Subjects in 40 CFR Part 799**

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

Dated: September 12, 1987.

**J.A. Moore,**

*Assistant Administrator for Pesticides and Toxic Substances.*

Therefore, 40 CFR Part 799 is 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 § 799.3450 by adding paragraphs (c)(1)(ii) and (iii) and (d), to read as follows:

**§ 799.3450 Propylene oxide.**

(c) \* \* \*

(1) \* \* \*

(ii) *Test standards.* The inhalation developmental toxicity testing shall be conducted in accordance with the EPA-approved study plans (July 22, 1987): "Range-finding Inhalation Developmental Toxicity Study in Rats" and "Inhalation Developmental Toxicity Study in Rats". Copies of these EPA-approved study plans are located in the rulemaking record for this rule (docket no. OPTS-42028D) and are available for inspection in EPA's OPTS Reading Room, NE-C004, 401 M Street SW., Washington, DC 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

(iii) *Reporting requirements.* (A) The developmental toxicity tests shall be completed and the final reports submitted to EPA within 12 months of the effective date of the final Phase II rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final Phase II rule.

(d) *Effective date.* The effective date of the final Phase II rule requiring inhalation developmental toxicity testing of propylene oxide is November 6, 1987.

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