

40 CFR Part 799

(OPTS-42084E; FRL 3458-1)

Commercial Hexane; New Definition of Test Substance and Effective Date

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the final test rule in 40 CFR 799.2155 on commercial hexane which was published in the Federal Register of February 5, 1988 (53 FR 3382). The rule was issued under section 4(a) of the Toxic Substances Control Act (TSCA). This amendment redefines the percentage of *n*-hexane in the test substance and extends the deadlines for submission of notices of intent to test, exemption applications, and test results. It also eliminates the 45-day waiting period between submission of study plans and the initiation of testing for neurotoxicity as required by this rule. **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 18, 1988. This rule shall become effective on November 17, 1988.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting 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 amending the final rule on commercial hexane by changing the specification of the test substance and the effective date and eliminating the 45-day waiting period between submission of neurotoxicity study plans and the initiation of neurotoxicity testing.

I. Background

EPA issued a final rule under TSCA section 4(a)(1)(B), published in the Federal Register of February 5, 1988 (53

FR 3382) that established health effects testing requirements for commercial hexane. It specified that the test substance conform to ASTM D1836 specifications and contain no more than 40 liquid volume percent *n*-hexane and no less than 10 liquid volume percent methylcyclopentane (MCP). It also established the effective date of the rule as March 21, 1988.

On March 25, 1988, the American Petroleum Institute (API) notified EPA that the *n*-hexane content of commercial hexane currently being manufactured did not meet the specifications of the test substance as promulgated (Ref. 1). According to API, the commercial hexane with the lowest percentage of *n*-hexane that is currently available in the market and that has potential for work place and consumer exposure contains about 55 liquid volume percent *n*-hexane (Ref. 1). On April 13, 1988, API (Ref. 3) requested that EPA modify the definition of the test substance and extend the reporting deadlines in the rule accordingly. From the new data, EPA concluded that a range of between 51 to 55 percent *n*-hexane formulation represented the minimum *n*-hexane content of a currently available commercial hexane product. Therefore, the change in the definition of the test substance requested by API was warranted.

On May 27, 1988 (53 FR 19315) EPA proposed to redefine the commercial hexane test substance as a mixture that contains at least 40 liquid volume percent but no more than 55 liquid volume percent *n*-hexane, and no less than 10 liquid volume percent MCP. In the final test rule (53 FR 3382), EPA stated that it wanted to test a commercial hexane that contained the smallest fraction of *n*-hexane so that the *n*-hexane would not mask the effects of MCP and six other carbon (C₆) isomers found in commercial hexane products. EPA retained this position when it proposed the revised definition.

On May 27, 1988, EPA also proposed that a new effective date be set for the test rule which would be 44 days after publication of this amendment of the test substance definition. The new effective date would allow an extension of dates for completion of testing, necessitated by the time consumed in proposing, receiving comment, and promulgating the change in the test substance definition.

II. Public Comments

EPA received a written comment from API supporting the proposed revision of the definition of the test substance and the proposed new effective date (Ref. 4).

On July 6, 1988, API informed EPA that it has a contractor who could begin neurotoxicity testing by October 1, 1988 (Ref. 5). To allow API to initiate neurotoxicity testing as soon as possible, EPA decided to eliminate the procedural requirement in 40 CFR 790.50(a)(1) which requires that study plans be submitted no later than 45 days before initiating each test. This change applies only to neurotoxicity testing of commercial hexane required under 40 CFR 799.2155(c)(7).

III. New Test Substance Definition

Based on confidential business information (CBI) on the *n*-hexane composition of currently available commercial hexane, EPA is redefining the commercial hexane test substance as a mixture that contains at least 40 liquid volume percent but no more than 55 liquid volume percent *n*-hexane, and no less than 10 liquid volume percent MCP.

IV. New Effective Date of the Test Rule

The new effective date of the final test rule (53 FR 3382) is November 17, 1988. This new date will allow an extension of the dates for completion of testing (Ref. 2) and for other submission requirements specified in 40 CFR 790.45 which are calculated from the effective date of the final test rule.

V. Elimination of 45-Day Waiting Period

The requirement under 40 CFR 790.50(a)(1) to submit study plans no later than 45 days before initiating each test does not apply to the neurotoxicity testing of commercial hexane required under 40 CFR 799.2155(c)(7). The test sponsor, however, must submit the neurotoxicity study plans to EPA before testing is initiated.

VI. Economic Analysis

A change in the test substance definition will not significantly alter the cost of testing. Thus, the economic analysis for the final test rule for commercial hexane is unchanged.

VII. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS-42084). This record includes information considered by the EPA in developing this amendment and appropriate Federal Register notices.

This record includes the following information:

A. Supporting Documentation

(1) Federal Register notices consisting of:

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(a) Notice of proposed test rule on MCP and commercial hexane (51 FR 17854; May 15, 1986).

(b) Notice of final test rule for commercial hexane and methylcyclopentane (53 FR 3382; February 5, 1988).

(c) Notice of proposed definition of test substance and effective date for commercial hexane test rule (53 FR 19315, May 27, 1988).

(2) Communications consisting of:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

B. References

(1) American Petroleum Institute (API) Letter from Martha A. Beauchamp, Director of Health & Environmental Affairs Department, to Charles Elkins, Director, Office of Toxic Substances, USEPA. (March 25, 1988.)

(2) USEPA, Letter from Susan F. Vogt, Deputy Director, Office of Toxic Substances, to Martha A. Beauchamp, API. (April 8, 1988.)

(3) API Letter from Martha Beauchamp to A. E. Conroy, Director, Office of Compliance Monitoring, Office of Pesticides and Toxic Substances and to Susan F. Vogt, USEPA. (April 13, 1988.)

(4) API Letter from Martha Beauchamp to the TSCA Public Docket Office, Office of Toxic Substances, USEPA. (June 22, 1988.)

(5) API, Phone conversation between Bob Fensterheim and Catherine Roman, Test Rules Development Branch, Office of Toxic Substances, USEPA. (July 6, 1988.)

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 in the TSCA Public Docket Office, Rm. NE-G004, 401 M Street SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except on legal holidays.

VIII. Other Regulatory Requirements

A. Executive Order 12291

EPA judged that the final test rule was not subject to the requirement of a Regulatory Impact Analysis under Executive Order 12291. EPA has

determined that the modifications to the rule do not alter this determination.

This amendment 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 response 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 test rule would not have a significant impact on a substantial number of small businesses. The modifications to the final rule made in this rule do not change this determination.

C. Paperwork Reduction Act

This Agency has determined that this rule does not change existing recordkeeping or reporting requirements nor does it impose any additional recordkeeping or reporting requirements on the public.

Send comments regarding this rule to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

List of Subjects in 40 CFR Part 799

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

Dated: September 21, 1988.

Victor J. Kimm,
Acting 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. 2063, 2611, 2625.

2. By revising § 799.2155(a)(2), (b), and (d) to read as follows:

§ 799.2155 Commercial hexane.

(a) * * *

(2) The commercial hexane test substance, for purposes of this section, is a product which conforms to the specifications of ASTM D1836 and contains at least 40 liquid volume percent but no more than 55 liquid volume percent *n*-hexane and no less than 10 liquid volume percent MCP.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including import) or process or intend to manufacture or process commercial hexane, as defined in paragraph (a)(1) of this section and other than as an impurity, from the effective date of the final rule to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests in accordance with Part 792 of this chapter, and submit data, or submit exemption applications, as specified in this section, Subpart A of this part, and Part 790 of this chapter for single-phase rulemaking. Persons who manufacture commercial hexane as a byproduct are covered by the requirements of this section. Notwithstanding § 790.50(a)(1) of this chapter, persons who notify EPA of their intent to conduct neurotoxicity testing in compliance with paragraph (c)(7) of this section may submit study plans for those tests less than 45 days before beginning testing provided that EPA receives the study plans before this testing begins.

(d) *Effective date.* (1) The effective date of § 799.2155 will be November 17, 1988.

(2) The guidelines and other test methods cited in this section are referenced as they exist on the effective date of the final rule.

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