ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42071B; FRL-3503-6]

Testing Consent Order for Octamethylcyclotetrasiloxane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule announces that EPA has signed an enforceable testing consent order with six manufacturers of octamethylcyclotetrasiloxane (OMCTS; CAS No. 556-67-2), who have agreed to perform certain chemical fate and environmental effects tests with OMCTS. OMCTS is added to the list of Testing Consent Orders in 40 CFR 799.5000 for which the export notification requirements of 40 CFR Part 707 apply.

EFFECTIVE DATE: January 10, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. EB-44, 401 M St., SW., Washington, DC 20460, (202) 554-1404.

SUPPLEMENTARY INFORMATION: Under procedures described in 40 CFR Part 790, six manufacturers have entered into a testing consent order with EPA in which they have agreed to perform certain chemical fate and environmental effects tests with OMCTS.

Public reporting burden for this collection of information is estimated to average 8 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. 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 St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

I. ITC Recommendation

In its 15th Report to EPA, published in the **Federal Register** of November 29, 1984 (49 FR 46931), the ITC recommended that OMCTS be considered for chemical fate and environmental effects testing. Chemical fate testing included water solubility, octanol/water partition coefficient, and biodegradation studies. The recommended environmental effects testing included acute toxicity testing with several species and, if indicated by the results of the acute tests, chronic toxicity tests with appropriate species.

II. Proposed Test Rule

In the **Federal Register** of October 30, 1985 (50 FR 45123), EPA issued a proposed test rule requiring that manufacturers and processors of OMCTS conduct chemical fate and environmental effects testing of OMCTS. Chemical fate testing included biodegradability testing in water and sediment using the eco-core method of Bourquin et al. (Ref. 1), aerobic and anaerobic biodegradability tests in soil, and a biodegradability test in a sludge system. Environmental effects testing included acute toxicity tests with rainbow trout, fathead minnow, bluegill, sheepshead minnow, silversides, daphnids, mysid shrimp, oyster, and freshwater and saltwater algae; chronic effects tests with a fish, daphnid, and mysid shrimp; bioconcentration tests with fathead minnows and oysters; a marine sediment toxicity test; and a reproduction test with mallard ducks. EPA based this testing on a finding of potential for unreasonable risk of injury to the environment under TSCA section 4(a)(1)(A) and a finding of substantial environmental exposure under section 4(a)(1)(B). These finds are more fully described in the proposed rule.

III. Testing Consent Order Negotiations

After issuing the proposed test rule on OMCTS, EPA amended the regulations for rulemaking to expedite the development of data for risk assessment by establishing the TSCA section 4 testing consent order process. A consent order is not based on formal findings and expedites testing while retaining the same TSCA penalty provisions applicable under rulemaking.

On March 18, 1988, the Silicones Health Council (SHC) submitted a proposal to EPA requesting EPA to develop a testing consent order for OMCTS (Ref. 2). The SHC proposal contained most of the testing that EPA had included in the proposed rule. EPA agreed to consider negotiating a consent order with the SHC and issued a notice, published in the **Federal Register** on April 6, 1988 (53 FR 11341), announcing the decision. This notice also announced the time and location of a public meeting to initiate testing negotiations on OMCTS and requested that all "interested parties" who wanted to participate in negotiations identify themselves to EPA by April 28, 1988.

Prior to the public meeting of April 20, 1988 the SHC drafted a consent order on OMCTS and submitted it to EPA for review (Ref. 3). This draft was modified by EPA and was discussed at the public meeting of April 20 and a revised draft was discussed at the meeting of May 11. By December 1, 1988, six OMCTS manufacturers: Dow Corning Corp., Union Carbide Corp., General Electric Co., Rhone-Poulenc Inc., Mobay Corp., and Wacker Silicones Corp., and two interested parties, the Silicones Health Council and the County of Onondaga, New York had signed the Testing Consent Order for OMCTS. The manufacturers agreed to perform certain chemical fate and environmental effects tests by specified dates according to the test standards in the Appendix of the Consent Order.

IV. Use and Exposure

OMCTS is a colorless oily liquid with a water solubility of approximately 50 ppb, a log soil-sorption coefficient of 4.45, a log octanol/water partition coefficient of 3.8, and a vapor pressure of 1 mm Hg at 20°C (Refs. 4 through 10).

Based on data submitted under section 8(a) of TSCA and by Dow Corning, the 1985 importation/production volume of OMCTS was 110 to 135 million pounds and is expected to increase about 10 percent per year (Ref. 10). Approximately 80 percent of the OMCTS produced or imported is used on-site as an intermediate in the production of polydimethylsiloxane polymers (Ref. 9 through 12). These polymers are used in making surfactants, propellants, lubricants, caulks, sealants, and rubber products (Refs. 9, 11, and 12). The remaining 20 percent of OMCTS is used in spray cleaners and polishes, in paper and textile sizing agents, in detergents, as a defoamer in inks and paints, and in cosmetic products such as colognes, hairsprays, and antiperspirants (Refs. 11 and 13).

The proposed rule on OMCTS included the results of several monitoring studies reporting the presence of organosilicones in rivers and estuaries, effluents, sludges, and sediments at several locations in the United States, Europe, and Japan. After publication of the proposed test rule, the SHC submitted the results of a monitoring study it had sponsored (Ref. 14). In this study, 15 sediment samples from 3 estuaries and 8 sediment samples from 4 freshwater sites were analyzed for OMCTS and organosilicon. Effluent and sludge samples from 3 waste water treatment plants were also analyzed. Organosilicon was found in 17 of 28 samples, but OMCTS was identified in only 1 sediment sample from the Rouge River, Detroit, and in 2 sludge cake samples. EPA has reviewed this study, and, although locations below manufacturing plants were not sampled, the study is sufficient to show that OMCTS is not a widespread environmental contaminant at concentrations exceeding 50 ppb.

V. Testing Program

A. Chemical Fate

SHC has reported that OMCTS is not biodegradable in water and sediment, but due to its volatility, will not persist in receiving waters and sediments (Ref. 15).

Under the Consent Order, the manufacturers have agreed to determine the solubility of OMCTS in freshwater and saltwater, its volatility half-life in freshwater and saltwater, and its biodegradability rate in a sediment/water system.

B. Environmental Effects

Several acute toxicity tests were summarized in the proposed rule. EPA judged all the test data inadequate because they were based on nominal test concentrations that exceeded the water solubility of OMCTS. Available bioconcentration data indicate that the bioconcentration factor for OMCTS in fish may be as high as 10,000.

On February 10, 1988, Dow Corning Corporation submitted the results of a recently completed daphnid chronic toxicity test with OMCTS to EPA under section 8 (d) and (e) of TSCA (Ref. 16). These data suggested that OMCTS was toxic to daphnids at a concentration as low as 10 ppb. Since similar adverse effects were seen in the daphnids exposed to the solvent control, EPA and Dow Corning consider these data unreliable and inadequate to assess the toxicity of OMCTS.

In the Consent Order, the manufacturers agreed to a tiered testing program. Tests agreed upon are presented in the following table.

TABLE.—TESTING PLAN FOR OMCTS

	Test methods	Start date [1]	Report date [1]
Tier I Tests			
Solubility test in fresh water	40 CFR 796.1860	8	10
Solubility test in salt water	40 CFR 796.1860	8	10
Aquatic half-life	Smith [2]	8	10
Aquatic biodegradation	Bourquin [3]	12	16
Acute toxicity, algae	40 CFR 797.1050	12	16
Acute toxicity, daphnid	40 CFR 797.1300	12	16
Acute toxicity, rainbow trout	40 CFR 797.1400	12	16
Acute toxicity, silverside or sheepshead minnow	40 CFR 797.1400	12	16
Acute toxicity, mysid shrimp	40 CFR 797.1930	12	16
Chronic toxicity, daphnid	40 CFR 797.1330	12	16
Bioconcentration, fathead minnow	40 CFR 797.1520	12	16
Tier II Tests [4]			
Fish early life stage test	40 CFR 797.1600	18	24
Sediment/invertebrate test	Adams [5]	18	24

[1] Months after the effective date.

[2] Smith, J.H., Bomberger, D.C. Jr., and Haynes, D.L. "Prediction of the volatilization rates of high-volatility chemicals from natural water bodies." *Environmental Science and Technology*. 14:1332-1337. (1980).

[3] Bourquin, A.W., Hood, M.A., and Garnas, R.I. "An artificial microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment." *Developments in Industrial Microbiology*. 18:185-191. (1977).

[4] Performed only if any LC50 from Tier I is <1 mg/l or the MATC from the daphnid chronic test is <0.1 mg/l.

[5] Adams, W.J., Kimerle, R.A., and Mosher, R.G. "Aquatic safety assessment of chemicals sorbed to sediments." In: "Aquatic Toxicology and Hazard Assessment." Seventh Symposium. ASTM STP 854. R.D. Caldwell, R. Purdy, and R.C. Bahner, Eds., American Society for Testing and Materials, Philadelphia, PA. pp. 429-453. (1985).

In tier I, the manufacturers will perform all the required chemical fate tests, the acute tests with algae, daphnid, rainbow trout, a marine fish, and mysid shrimp, and a bioconcentration test with fathead minnows, and will repeat the chronic toxicity test with daphnids. Tier II testing includes a fish early life stage toxicity test and a test to determine sediment toxicity to benthic invertebrates. Tier II tests will be performed only if any of the LC50's from the tier I tests are ≤ 1 mg/l, or the maximum acceptable toxicant concentration (MATC) from the daphnid chronic test is ≤ 0.1 mg/l. If no such adverse effects are observed in any of the tier I tests, tier II testing is not required.

EPA is not requiring that the manufacturers perform all the acute tests that were identified in the proposed rule. EPA believes that if acute toxicity is observed, data on five species are sufficient to assess the acute toxicity of OMCTS to aquatic organisms. EPA is not including a mysid chronic test in tier II because EPA believes that both the toxicity data from the daphnid life cycle test, and, if triggered, the fish early life stage test and the sediment test with the midge, will be sufficient to assess the chronic toxicity of OMCTS.

EPA is not requiring a reproduction test in mallard ducks because available health effects data demonstrate that OMCTS is not toxic to mammals, and thus is not expected to be toxic to ducks. The rat oral LC50 is >2.0 g/kg and antifoam A (5 percent OMCTS) had no adverse effects on rats in a 2-year feeding study (Ref. 17).

The manufacturers agreed to perform the testing according to cited EPA test standards and a specified test schedule. Tier I testing will be completed in 16 months with interim status reports due 6 and 12 months after the date of publication of this notice. If tier II testing is required, it will be completed in 24 months with an interim status report due after 18 months.

EPA and the manufacturers recognize that OMCTS is a volatile substance that is soluble in water at extremely low concentrations and that a test method does not exist to measure OMCTS at concentrations below 30 ppb. Also, additional efforts are needed to develop test systems that can generate stable concentrations of OMCTS in water. The manufacturers will work on the development of such methods and test systems during the period after signature of the Consent Order and before the first test in tier I is performed.

EPA will use the data generated by these tests to determine the risk of adverse environmental effects associated with the manufacture, use, and disposal of OMCTS.

VI. Export Notification

The issuance of this Testing Consent Order subjects any person who exports or intends to export OMCTS to the export notification requirements of section 12(b) of TSCA. The specific requirements are listed in 40 CFR Part 707. In 52 FR 23548 of June 23, 1987, EPA issued 40 CFR 799.5000 as a listing of testing consent orders issued by EPA. This listing serves as notification to persons who export or who intend to export chemical substances or mixtures which are the subject of testing consent orders that 40 CFR Part 707 applies.

VII. Rulemaking Record

EPA has established a record for this rule (docket number OPTS-42071B). This record contains the information EPA considered in developing this rule and the Consent Order and includes the following information.

A. Supporting Documentation

(1) Testing Consent Order for OMCTS.

(2) **Federal Register** notices pertaining to this rule and Consent Order consisting of:

(a) Notice containing the ITC designation of OMCTS to the Priority List (49 FR 46931; November 29, 1984).

(b) Rules requiring TSCA section 8(a) and 8(d) reporting on OMCTS (49 FR 46739 and 46741; November 28, 1984).

(c) Notice of EPA's proposed test rule for octamethylcyclotetrasiloxane (50 FR 45123; October 30, 1985).

(d) Notice soliciting interested parties for developing a Testing Consent Order for OMCTS (53 FR 11341; April 6, 1988).

(3) Communications consisting of:

(a) Written letter.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(4) Reports—published and unpublished materials.

B. References

(1) Bourquin, A.W., Hood, M.A., and Garnas, R.I. "An artificial microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment." *Development in Industrial Microbiology*. 18:185-191. (1977).

(2) Silicones Health Council. Letter from E.J. Hobbs to Stephen Ells, Environmental Protection Agency. (March 18, 1988).

(3) Silicones Health Council. Draft Testing Consent Order on OMCTS. (April 13, 1988).

(4) Dow Corning Corporation. Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. (December 12, 1984).

(5) Vogel, G.E. and Stark, F.O. "Mutual solubilities in water-permethylsiloxane system." *Journal of Chemical Engineering Data*. 9(4):555-601. (October 1984).

(6) Bruggemen, W.A. et al. "Absorption and retention of polydimethylsiloxanes (Silicones) in fish: preliminary experiments." *Toxicology and Environmental Chemistry*. 7(4):287-296. (1984).

(7) Dow Corning Corporation. Unpublished study of T.H. Lane and C.I. Frye. Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. (December 12, 1984).

(8) Kenaga, E.E., "Predicted bioconcentration factors and soild sorption coefficients of pesticides and other chemicals." *Ecotoxicology and Environmental Safety*. 4:26-38. (1980).

(9) Interagency Testing Committee (ITC). Fifteenth Report to the Administrator and Request for Comments. (November 29, 1984).

(10) Dow Corning Corporation. Letter with attachment from C.W. Lentz to Martha Price, Environmental Protection Agency. (February 27, 1986).

(11) Dow Corning Corporation. Letter with attached studies from E.J. Hobbs to M. Grief, Interagency Testing Committee. (December 16, 1982).

(12) Browning, G.R. Silicone Products Division, General Electric Co. Personal communication with M.G. Price, U.S. Environmental Protection Agency. (May 23, 1985).

(13) Versar, Inc. Environmental risk assessment for octamethaylcyclotetrasiloxane. Springfield, VA (1986).

(14) Ann Arbor Technical Services, Inc. Organosiloxanes in fresh water and salt water sediments. Ann Arbor, MI. (1985).

(15) Silicones Health Council. Comments of the Silicones Health Council on EPA's proposed test rule for octamethylcyclotetrasiloxane. (February 28, 1986).

(16) Dow Corning Corporation. A chronic reproductive limit test of polyethylene glycol sorbitan monolaurate and

octamethylcyclotetrasiloxane with *Daphnia magna*. (1988).

(17) CRCS, Inc. Information Review No. 548. Octamethylcyclotetrasiloxane. Reston, VA (May 31, 1983).

A public version of this record is available for inspection in the OPTS Reading Rm. NE-G004, 401 M St. SW., Washington, DC, from 8 a.m. to 4 p.m. Monday through Friday, except legal holidays.

VIII. Other Regulatory Requirements

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of this Paperwork Reduction Act, 44 U.S.C. *et seq.* and have been assigned OMB control number 2070-0033.

Public reporting burden for this collection of information is estimated to average 8 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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 St., SW., Washington, DC 20460; and to 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

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

Dated: December 28, 1988.

Susan F. Vogt,

Acting Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

Therefore, 40 CFR Part 799 is amended as follows:

1. The authority citation continues to read as follows:

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

2. Section 799.5000 is amended by adding the following chemical substance in Chemical Abstract Service (CAS) Registry Number order to the table to read as follows:

§ 799.5000 Testing consent orders.

* * * * *

CAS No.	Substance or mixture name	Testing	Federal Register citation
556-67-2	Octamethylcyclo-tetrasiloxane	Chemical fate	[Insert FR date].
		Environmental effects	[Insert FR date].

[FR Doc. 89-298 Filed 1-9-89; 8:45 am]

BILLING CODE 6560-50-M