

**40 CFR Part 799**

[OPPTS-42166A; FRL-4575-8]

**Testing Consent Order for Refractory Ceramic Fibers****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This notice announces that EPA has signed an enforceable testing consent order under the Toxic Substances Control Act (TSCA), 15 U.S.C. section 2601 et seq., with three of the primary producers of refractory ceramic fibers (RCF), who have agreed to perform workplace exposure monitoring of RCFs for all workplace activities, and report this information to the Agency. Pursuant to 40 CFR 790.22, the RCFs testing consent order is being added to the list of Testing Consent Orders in 40 CFR 799.5000. Accordingly, the export notification requirements of 40 CFR part 707 apply to RCFs.

**EFFECTIVE DATE:** May 14, 1993.**FOR FURTHER INFORMATION CONTACT:**

Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

**SUPPLEMENTARY INFORMATION:****I. Regulatory History**

On November 21, 1991, the Agency concluded that, based on animal inhalation data submitted to the Agency under section 8(e) of TSCA, RCFs may present an unreasonable risk of cancer to human health. After conducting an accelerated review of RCF under section 4(f), the EPA Administrator concluded there was not sufficient data available to determine whether or not RCFs present an unreasonable risk. However, there was sufficient basis for concern to initiate a regulatory investigation of RCFs to determine whether action under TSCA section 6 was appropriate. The regulatory investigation of RCFs includes a thorough review of a recently completed multiple dose animal inhalation study, an update of the findings from an ongoing worker epidemiology study, an analysis of substitutes, and comprehensive exposure data. This is an ongoing investigation that will not be complete until the Agency has sufficient data to determine whether RCFs pose an unreasonable risk.

During the accelerated review, one area identified as needing additional

data was worker exposure to RCFs. Under section 4 of TSCA, EPA may require the testing of chemical substances and mixtures by adopting enforceable consent agreements or promulgating test rules. In light of three of the primary producers' willingness to work with EPA on the development of this type of data, EPA decided to develop an enforceable testing consent order according to the procedures outlined in 40 CFR part 790.

Accordingly, on August 17, 1992 (57 FR 36997), EPA issued a **Federal Register** notice requesting that persons interested in participating in exposure testing negotiations for RCFs, identify themselves to EPA. The notice announced the date for a public meeting to initiate testing negotiations for RCFs. The primary goal of the negotiations was to develop an exposure testing program to monitor workplace exposures throughout the RCF lifecycle (i.e., manufacturing, fabrication, processing, installation, and removal) for all workplace activities. Negotiations began in September 1992 with the Refractory Ceramic Fibers Coalition (RCFC), a trade organization that focuses on research, product stewardship, and regulatory issues relevant to RCFs; primary manufacturers of RCFs; and other interested parties (e.g., labor and user groups). The negotiation participants developed workplace and worker sampling schemes, protocols for the collection and analysis of fibers, and provisions for evaluation of the resulting data. The negotiations were completed on November 10, 1992.

This **Federal Register** document announces the completion of the enforceable testing consent order which is the final product of negotiations, and represents the consensus of EPA and negotiation participants.

In addition to developing the exposure monitoring consent order with EPA, RCFC has developed and implemented a Product Stewardship Program (PSP). The program consists of seven elements: Health effects research, workplace exposure monitoring, workplace exposure control measures, exposure assessments, product research, special studies, and a communications program. EPA is particularly encouraged by the commitment of RCFC to monitor workplace exposures to RCFs, and to look for ways to reduce exposures. EPA believes that such a program is a significant step towards the reduction in the risk of RCFs. Results from the exposure testing consent order should help determine the effectiveness of industry's stewardship of RCFs.

**II. Use and Exposure**

RCFs are defined as amorphous man-made fibers produced from the melting and "blowing" or "spinning" of calcined kaolin clay or a combination of alumina ( $Al_2O_3$ ) and silica ( $SiO_2$ ). Oxides such as zirconia oxide, ferric oxide, titanium oxide, magnesium oxide, calcium oxide, and alkali oxides may be added. The approximate percentage of components (by weight) may vary as follows: alumina, 20 to 80 percent; silica, 20 to 80 percent; zirconia, 0 to 20 percent; and other oxides in lesser amounts, approximately 1 to 5 percent (CAS number 142844-00-6).

RCFs are processed by two different methods: The "spinning" process and the "blowing" process. The resultant fiber is vitreous and non-crystalline. RCFs are fabricated into a wide variety of forms. Fiber diameters vary within the product, ranging from approximately 0.06 micron to greater than 3 microns. Lengths in the final product also vary and are dependent upon the processing used.

RCFs are used primarily for high temperature industrial insulation applications, most frequently as refractory lining in high temperature furnaces, heaters, and kilns in industries such as ethylene, steel, aluminum, ceramics, and glass production. RCFs are also used in automotive applications, aerospace uses, and in certain commercial appliances such as self-cleaning ovens.

RCFs are currently produced by six companies in the United States at eight locations. The Carborundum Company, Premier Refractories and Chemicals, Inc., and Thermal Ceramics Inc., together account for the bulk of U.S. production of RCFs. The three other domestic producers, A.P. Green Industries, ELTECH Thermal Systems Corporation, and Industrial Insulation, Inc. produce RCFs in relatively small quantities. Approximately 80 million pounds of RCFs were produced in the U.S. in 1990.

**III. Health Effects**

Several studies show that RCFs are an animal carcinogen, and EPA has classified RCF as a probable human carcinogen. A major animal inhalation study using kaolin, the most common type of RCF, has shown a positive tumorigenic response in rats and hamsters, with 35 percent of the hamsters exposed to kaolin RCFs developing pleural mesothelioma, and 13 percent of the rats exposed to kaolin RCFs developing adenoma-carcinomas. Additional results from this study also

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indicate the development of pleural and pulmonary fibrosis in both rats and hamsters exposed to kaolin RCFs. In addition, this study has shown fibrogenic and tumorigenic responses in rats exposed to other types of RCF. See the docket for the November 21, 1991 section 4(f) **Federal Register** Notice, 56 FR 58693, for references to these studies.

#### IV. Testing Consent Order Negotiations

On September 2, 1992, EPA held a public meeting to initiate negotiations of the Consent Order, pursuant to 40 CFR part 790. The meeting brought together the three primary domestic manufacturers of RCFs (the RCFC member companies), as well as representatives from processor and user groups, organized labor, and fiber glass and rock wool manufacturers.

The primary goals for the workplace exposure monitoring program developed in the Consent Order, are to provide a baseline for occupational RCF exposure, a study of trends in exposure levels over time (the Consent Order requires testing for a minimum of 5 years), and a study of differences in workplace concentrations among employers engaged in various tasks.

While the parties have agreed to conduct the monitoring for a minimum of 5 years, EPA is not precluded from taking regulatory action at any time should EPA receive information that indicates a need to do so. Additionally, if testing under the Consent Order is invalidated, not conducted, or EPA determines that additional testing is necessary, EPA may initiate rulemaking procedures under TSCA section 4. As part of any such rulemaking proceedings, EPA would make statutory findings pursuant to section 4.

This Consent Order and the resultant data will be representative of worker exposures for the participating RCF manufacturers and some of their customers. EPA does not have information necessary to demonstrate whether the exposure data would be representative of workplace conditions for employees of non-participating manufacturers, processors, or end-users of RCFs. The following units (V., VI., VII., and VIII.) summarize the terms and conditions of the RCF Testing Consent Order. The full Consent order is included in the record for this rulemaking.

#### V. Monitoring Program

The three primary producers of RCFs have agreed to obtain 720 air monitoring samples to monitor RCF exposures annually from their own facilities that manufacture and process RCFs (320

samples) as well as from their customers' facilities (400 samples). The samples will be collected from employees engaged in all aspects of RCF production and use.

Eight functional activity categories have been defined for the monitoring. The eight categories are: Fiber production (manufacturing sector only), finishing, installation, removal, assembly operations, mixing/forming, auxiliary operations, and other activities (which include papermaking, production of textiles, and automotive activities). The last seven categories are for manufacturing, processing, and end-use sectors. These categories were intended to cover all RCF-related workplace activities. The customers to be selected will include those selected at random and those who specifically request monitoring.

RCFC has also agreed to monitor silica (as well as RCFs) exposures to workers involved in the after-service removal of RCFs from high temperature ovens and furnaces.

#### VI. Standards and Methodologies

RCF inhalation exposures for workers will be measured using phase contrast microscopy (PCM). The analytical protocol which will be employed was developed for fiber measurement by the National Institute for Occupational Safety and Health (NIOSH) and is called the NIOSH Method 7400. Analysis of the RCFs will follow the alternate counting rules for this method (commonly referred to as the "B rules").

RCFC will analyze a subset of samples (6 percent) on an annual basis by transmission electron microscopy (TEM) to ensure that the phase contrast microscope is capable of resolving the predominance of fibers. This data will be analyzed and reported to EPA for evaluation.

Due to exposure to high temperature over time, it is possible for RCFs to undergo a partial transformation to cristobalite, a form of crystalline silica. Concern was expressed in the negotiations that silica exposures should be measured in the workplaces where RCFs might be severely disturbed, as in removal activities. The Consent Order contains an appendix requiring RCFC to monitor the after-service removal of RCFs from end-user applications. Specifically, RCFC will monitor workers involved in removing RCFs from high temperature ovens and furnaces for both RCF and silica exposures. Two samples will be collected from the workers to be monitored. The RCF sample will be analyzed by NIOSH Method 7400 to determine the fiber concentration. The

silica sample will be analyzed by NIOSH Method 7500 which specifies the procedures to follow for determining silica exposure.

All testing will be conducted in accordance with the sampling and analytical protocols set forth in Appendices 1, 2, 3, 4, 5, and 6 of the Consent Order. RCFC has agreed to meet with EPA every 6 months to review data submissions and discuss whether test standard modifications are necessary. Modifications to the Consent Order will be governed by 40 CFR 790.68.

#### VII. Reporting Requirements

The signatories of this Consent Order, through RCFC, will submit monitoring data every 6 months beginning 6 months after the initiation of testing. The signatories agree to meet with EPA no later than 45 days after the submission of the data to review the data submission collected according to the Consent Order. The signatories will conduct the exposure monitoring for a minimum of 5 years. Data submitted to EPA under the Consent Order will be available in the Public Docket and will be identified by Docket Number OPPTS-42166A and Refractory Ceramic Fibers - Exposure Monitoring Data.

#### VIII. Export Notification

The signatories of this Consent Order are required to comply with the notification requirements of section 12(b)(1) of TSCA and 40 CFR part 707 if they export or intend to export RCFs. Any other person who exports or intends to export RCFs is also subject to these export requirements as a result of this testing consent order under TSCA section 4. Chemicals subject to testing consent orders are listed at 40 CFR 799.5000. This 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.

Section 12(b)(1) of TSCA reads: "If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(b), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture."

40 CFR part 707 includes the following sections that govern notices of export under section 12(b) of TSCA: § 707.60 discusses applicability and compliance of TSCA section 12(b); § 707.63 discusses pertinent definitions;

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§ 707.65 deals with submissions of export notification to the EPA; § 707.67 outlines the required contents of export notification; § 707.69 addresses the notification EPA must send to the importing foreign governments; § 707.72 states procedures for termination of reporting requirements; and § 707.75 discusses confidentiality.

#### IX. Other Regulatory Requirements

To the extent this collection of information is covered by the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., data will be collected under OMB Control No. 2070-0033.

Public reporting burden for the collection of information from customers of the three primary manufacturers is estimated to average 10 minutes per response (approximately 43 hours per year). The estimated average includes time for answering a list of questions that an industrial hygienist will routinely ask with regard to the exposure monitoring program.

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 Management and Budget, Paperwork Reduction Project (2070-0033), Washington, DC 20503.

#### X. Record

EPA has established a record for this testing consent order under Docket Number OPPTS-42166A. This record contains the information EPA considered in developing this Consent Order and includes the following information.

##### A. Support Documents

1. Testing consent order for RCFs and Appendices 1 through 6.

2. Federal Register notices consisting of:

a. August 17, 1992 Notice announcing a public meeting for September 2, 1992, and soliciting interested parties to develop a consent order for RCFs (57 FR 36997).

b. November 21, 1991 Notice announcing 4(f) decision on RCFs (56 FR 58693).

3. EPA's May 20, 1992 Decision Memorandum for RCFs.

4. Communications consisting of:

a. Meeting notes from September 2, 1992, September 16, 1992, September 24, 1992, October 8, 1992, October 21, 1992, and November 10, 1992.

b. "Sampling Plan and Associated Analytical Protocol for Monitoring Workers Engaged in the Manufacture or Processing of RCFs," draft November 2, 1992 (D. Maxim/Everest Consulting).

c. "Sampling Plan and Associated Analytical Protocol for Monitoring Workers Engaged in the Manufacture or Processing of RCFs," final November 25, 1992 (D. Maxim/Everest Consulting).

d. "Responses to Protocol Related Issues," October 8, 1992 (D. Maxim/Everest Consulting).

e. "Proposed Sampling Plans for Discussions with EPA and Other Interested," October 21, 1992 (D. Maxim/Everest Consulting).

f. "Background and Concepts for 'Scope' Discussions with EPA and Other Interested," October 8, 1992 (D. Maxim/Everest Consulting).

g. EPA Memorandum "EPA Proposal for the Selection of Firms to be Monitored," November 18, 1992 (M. Henshall/EPA-RCF Project Coordinator to Negotiation Participants).

h. Two EPA Memoranda, December 7, 1992, from M. Henshall (EPA-RCF Project Coordinator) to RCF Negotiation Participants requesting comments on final background document.

i. EPA Memorandum "EPA Response to RCFC Proposed Sampling Plans for Discussions with EPA and Other Interested," Dated October 21, 1992," from M. Henshall (EPA-RCF Project Coordinator) to RCF Negotiation Participants, November 29, 1992.

j. North American Insulation Manufacturers Association (NAIMA) letter, dated February 16, 1993, to Ms. Jellinek (EPA-RCF Project Coordinator) re: Comments on the RCF Consent Agreement; facsimile referenced in NAIMA letter to Chuck Axten, et al. from Walter Eastes (Owens-Corning) re: Airborne Fiber Counting Rules.

k. Letter from D. Maxim (Everest Consulting), dated February 22, 1992, to EPA staff member Ms. Jellinek re: Comments on the RCFs Consent Agreement.

l. Memorandum from D. Cox (Cox Associates/EPA consultant) to EPA staff member Betsy Dutrow, et al. dated October 7, 1992, re: Comparison of "A" Rules and "B" Rules and number of TEM samples needed.

m. EPA Memorandum from D. Cox (Cox Associates) to M. Conomos (EPA

staff member) dated November 13, 1992, re: Selection of firms to be monitored in RCF study.

n. EPA Memorandum from M. Conomos and B. Dutrow (EPA staff members) to RCFs Negotiation Participants and Interested Parties, dated October 22, 1992, re: Number of TEM Analyses to be conducted as part of RCFs Workplace Monitoring Study.

o. EPA Memorandum from Joseph S. Carra (Deputy Director, Office of Pollution Prevention and Toxics) to File, dated December 23, 1992, re: Recording conversation with William P. Kelly, President of RCFC and Robert Malone, President of Carborundum

p. EPA Memorandum from A. Jellinek (EPA-RCF Project Coordinator) to Negotiation Participants dated March 15, 1992.; "Response to Comments submitted by Dan Maxim, NAIMA, and Denny Christensen, for RCF Exposure Monitoring Consent Order Final Draft."

#### B. References

a. "Nomenclature of Man-Made Vitreous Fibers;" April 15, 1991 (TIMA).

b. "Air Sampling Protocol - Fibers and Free Silica;" revised November 1991 (Dept. of Health, University of Cincinnati).

c. "RCF Emissions from Domestic Production Facilities and Landfill: Data Quality Objectives;" 1990 (M. Conomos and B. Dutrow, EPA).

d. "EPA Office of Toxic Substances Guidance Document for Preparation of the Quality Assurance Project Plan," November 1, 1987 (EPA).

Dated: April 26, 1993.

Victor J. Kimm,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR Chapter 1, subchapter R, 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. Section 799.5000 is amended by adding refractory ceramic fibers to the table in CAS Number order, to read as follows:

§ 799.5000 Testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers.

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CAS Number	Substance or mixture name	Testing	FR Publication Date
142844-00-6	Refractory ceramic fibers	Exposure monitoring	May 14, 1993.

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