

Refractory ceramic fibers; CASRN Not found

Human health assessment information on a chemical substance is included in the IRIS database only after a comprehensive review of toxicity data, as outlined in the [IRIS assessment development process](#). Sections I (Health Hazard Assessments for Noncarcinogenic Effects) and II (Carcinogenicity Assessment for Lifetime Exposure) present the conclusions that were reached during the assessment development process. Supporting information and explanations of the methods used to derive the values given in IRIS are provided in the [guidance documents located on the IRIS website](#).

STATUS OF DATA FOR Refractory ceramic fibers

File First On-Line 09/01/1992

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	not evaluated	
Inhalation RfC (I.B.)	not evaluated	
Carcinogenicity Assessment (II.)	yes	09/01/1992

I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — Refractory ceramic fibers

CASRN — Not found

Not available at this time.

I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name — Refractory ceramic fibers

CASRN — Not found

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Refractory ceramic fibers

CASRN — Not found

Last Revised — 09/01/1992

Section II provides information on three aspects of the carcinogenic assessment for the substance in question; the weight-of-evidence judgment of the likelihood that the substance is a human carcinogen, and quantitative estimates of risk from oral exposure and from inhalation exposure. The quantitative risk estimates are presented in three ways. The slope factor is the result of application of a low-dose extrapolation procedure and is presented as the risk per (mg/kg)/day. The unit risk is the quantitative estimate in terms of either risk per ug/L drinking water or risk per ug/cu.m air breathed. The third form in which risk is presented is a drinking water or air concentration providing cancer risks of 1 in 10,000, 1 in 100,000 or 1 in 1,000,000. The rationale and methods used to develop the carcinogenicity information in IRIS are described in The Risk Assessment Guidelines of 1986 (EPA/600/8-87/045) and in the IRIS Background Document. IRIS summaries developed since the publication of EPA's more recent Proposed Guidelines for Carcinogen Risk Assessment also utilize those Guidelines where indicated (Federal Register 61(79):17960-18011, April 23, 1996). Users are referred to Section I of this IRIS file for information on long-term toxic effects other than carcinogenicity.

NOTE: Refractory ceramic fibers (RCFs) are synthetic, vitreous, noncrystalline, aluminum silicate-based fibers. They are produced by melting kaolin clay, or a mixture of alumina (Al₂O₃) and silica (SiO₂), and then spinning or blowing the melt to form elongated particles at least 3 times longer than wide (aspect ratio >3). Up to 20% of zirconia (ZrO₂), and about 1-5% of other metallic oxides (TiO₂, Cr₂O₃, Fe₂O₃, MgO, etc.) are sometimes added in the process to produce specialty RCFs (e.g., zirconia RCF) for specific high-temperature applications. Fiber diameters and lengths vary within the products; the average diameters of most RCFs produced in the U.S. are 2.0-3.5 microns but can range from <1 micron to about 12 microns. Under some use conditions at temperatures above 1000 degrees C, crystalline silica may be generated from manufactured RCF products (IARC, 1988; U.S. EPA, 1988).

II.A. Evidence for Human Carcinogenicity

II.A.1. Weight-of-Evidence Characterization

Classification — B2; probable human carcinogen

Basis — No human data and sufficient evidence from animal studies. Chronic inhalation studies showed that several types of RCFs induced mesotheliomas and lung tumors in rats and hamsters. Administration of RCFs by intraperitoneal/ intrapleural injection or intratracheal instillation also caused peritoneal/ pleural mesotheliomas or lung tumors in rats and hamsters.

II.A.2. Human Carcinogenicity Data

None.

II.A.3. Animal Carcinogenicity Data

Sufficient. There are three chronic inhalation studies on RCFs in rats and two on hamsters.

Davis et al. (1984) studied the effects of long-term inhalation exposure to ceramic aluminum silicate glass in rats. In this study, a group of 48 SPF Wistar rats (AF/HAN strain; sex unspecified) was exposed to the test fibers at 8.4 mg/cu.m (95 fibers/mL; fibers were <3 um in diameter and >5 um in length) for 7 hours/day, 5 days/week, for 12 months. Interim sacrifices of four animals were made at 12 and 18 months. The remaining rats were killed at 32 months. The survival rates of the treated and control groups were similar. A total of eight exposed animals developed pulmonary neoplasms (1 adenoma, 3 carcinomas, 4 malignant histiocytomas) and one had peritoneal mesothelioma. No pulmonary tumors of any type were found in the 40 unexposed control rats.

In another chronic inhalation study (Carborundum, 1990; Manville, 1991a), groups of 124 male Fischer 344 rats were exposed, 6 hours/day, 5 days/week, for 24 months, to 30 mg/cu.m (approximately 250 fibers/mL) of four different types of RCF: 1) kaolin RCF (0.96 um in diameter and 24.2 um in length); 2) zirconia RCF (1.07 um in diameter and 18.5 um in length); 3) high purity kaolin RCF (1.29 um in diameter and 30.98 um in length); or 4) "after service" RCF (>15 um in length, diameter unspecified; a kaolin-based ceramic fiber, containing 27% crystalline silica, that had previously been exposed to high temperatures). The positive controls received chrysotile asbestos at 10 mg/cu.m (fibers >5 um in length, diameter unspecified). A group of negative controls was exposed to filtered air only. The preliminary results of this study showed statistically significant increased incidences of lung neoplasms in all animal groups exposed to RCF. The incidences of total lung tumors (adenoma and carcinoma) in different animal groups were: negative control (air): 2/124 (1.6%); positive control (chrysotile): 12/63 (19.0%); kaolin RCF: 18/124 (14.6%); zirconia RCF: 11/124 (8.8%); high purity kaolin RCF: 17/124 (13.7%); "after service" RCF: 4/124 (3.2%). Increased incidences of pleural mesotheliomas were also observed in 3 out of 4 types of RCF [kaolin RCF: 2/124 (1.6%); zirconia RCF: 3/124 (2.4%);

high purity kaolin RCF: 2/124 (1.6%)]. Although the incidences of these mesotheliomas are not statistically significantly different from that of the negative controls (0/124), they are considered biologically significant since mesotheliomas are not known to occur in experimental animals spontaneously.

Carborundum (1990) also conducted a single-dose chronic inhalation study with kaolin RCF in hamsters. A group of 140 male Syrian hamsters were exposed to airborne kaolin RCF at 30 mg/cu.m (approximately 200 fibers/mL; fibers were 0.96 μ m in diameter and 24.2 μ m in length) 6 hours/day, 5 days/week, for 18 months. A positive control group consisting of 80 male hamsters were administered chrysotile asbestos at 10 mg/cu.m (approximately 5000 fibers/mL; fibers >5 μ m in length, diameter unspecified). Preliminary results showed a 35% (36/102) incidence of malignant mesothelioma with moderate lung and pleural fibrosis in hamsters exposed to kaolin RCF. Nonmalignant pleural mesothelial growth with lung fibrosis was found in one of the chrysotile asbestos-exposed hamsters. No such neoplasms occurred in 73 negative control hamsters inhaling filtered air only.

Smith et al. (1987) studied the long-term health effects of refractory ceramic fibers in rats and hamsters. Female Osborne-Mendel rats and male Syrian hamsters were exposed to RCF (type unspecified, presumably kaolin RCF) at 12 mg/cu.m (approximately 200 fibers/mL) by inhalation ("nose-only") for 6 hours/day, 5 days/week, for 24 months. Approximately 83% of the fibers were >10 μ m in length and 86% were <2 μ m in diameter (the mean diameter of the fibers was 1.8 μ m). No pulmonary neoplasms were observed in the exposed rats (0/55) in this study. None of the exposed hamsters developed any lung tumors (0/70), but malignant mesothelioma was found in one hamster (1/70). With the exception of one bronchoalveolar tumor in a sham control hamster (exposed to filtered air) (1/58), none of the other sham controls or unmanipulated cage controls developed pulmonary or pleural tumors. [It should be noted that in this study, UICC crocidolite asbestos (positive control) only produced a low tumor incidence in rats (3/57; 1 mesothelioma, 2 bronchoalveolar tumors) and no tumors in hamsters.]

The carcinogenicity of RCFs has also been demonstrated in rats and hamsters by intraperitoneal/intrapleural injection or intratracheal instillation that are widely used for the study of the carcinogenic effects of asbestos and alternative fibers.

Pott et al. (1989, 1991) showed that ceramic aluminum silicate fibers are carcinogenic in rats via the intraperitoneal route. In one study (Pott et al., 1989), suspensions of either Ceramic "Fiberfrax" dust (50% <0.89 μ m in diameter; 50% <13 μ m in length) or ceramic "MAN" (50% <1.4 μ m in diameter; 50% <16 μ m in length) were injected into the abdominal cavity of female Wistar rats at five weekly doses of 9 mg of "Fiberfrax" (a total dose of 45 mg) or 15 mg of "MAN" (a total dose of 75 mg). High incidences of peritoneal tumors (mesothelioma or sarcoma) were observed 130 weeks after the first treatment in animal groups treated with

ceramic "Fiberfrax" (33/47 or 70.2%) and with ceramic "MAN" (12/54 or 22.2%). Under similar experimental conditions, UICC chrysotile asbestos induced comparable incidences of peritoneal tumors in a dose-related manner but at considerably lower doses (12/36, 23/34 and 30/36 at 0.05, 0.25 and 1.0 mg, respectively). Only 2/102 rats in the saline control group had a peritoneal tumor.

In another study by Pott et al. (1991), four RCF samples were tested. Groups of 36 female Wistar rats received intraperitoneal injections of either: 1) a single dose (12 mg) of "Fiberfrax" I (median diameter: 0.47 μm ; median length: 5.5 μm); 2) a single dose (12 mg) of "Fiberfrax" II (median diameter: 0.84 μm ; median length: 13.1 μm); 3) 2 weekly doses (20 mg each) of "Fiberfrax" II (median diameter: 0.84 μm ; median length: 13.1 μm); or 4) 2 weekly doses (20 mg each) of "Manville" (median diameter: 1.35 μm ; median length: 16.4 μm). The incidences of peritoneal tumors (mesothelioma or sarcoma) observed in the respective animal groups after 131 weeks were: 1) 15/35 (42.9%); 2) 17/36 (47.2%); 3) 29/36 (80.6%); and 4) 6/36 (16.7%). None of the 34 control rats, which received i.p injections (50 doses, 1 mL each) of saline, had such neoplasms.

A group of 32 SPF Wistar rats of the AF/HAN strain (sex unspecified) received a single intraperitoneal injection of 25 mg of fibrous ceramic aluminum silicate glass (Davis et al., 1984). The injected fibers were predominately short and thin (90% <0.3 μm in diameter and <3 μm long). Three of the 32 treated rats developed peritoneal tumors (1 mesothelioma, 2 fibrosarcoma) approximately 850 days after injection. No negative controls were used in this study. The authors indicated that the low incidence of tumors observed in this study is probably because of the use of short fibers (90% <0.3 μm in length).

Smith et al. (1987) reported that an RCF (type unspecified, presumably kaolin RCF) was carcinogenic in female Osborne-Mendel rats and male Syrian hamsters when intraperitoneally injected at a single dose (25 mg in 0.5 mL saline) into these animals at 100 days of age. The animals were then maintained for the duration of their lives. Approximately 86% of the fibers used were <2.0 μm in diameter and 83% were >10 μm in length. The mean diameter of the fibers was 1.8 μm . Rats injected with RCF had significantly reduced mean lifespans resulting from the induction of abdominal mesotheliomas. At necropsy about 15 months after i.p. injections, 19/23 (83%) rats had developed peritoneal mesothelioma. The incidences of peritoneal mesothelioma in the hamsters were 13% (2/15) in one treated group and 24% (5/21) in a second treated group. Eighty-three percent (19/23) of the rats and 40% (8/25) of the hamsters injected with crocidolite asbestos (positive control) had abdominal mesotheliomas at their deaths. Negative saline controls and unmanipulated control animals had no tumors.

When the RCF (same type and dimension used in the above experiments) was administered to the rats and hamsters by intratracheal instillation (2 mg in 0.2 mL saline, once a week for 5 weeks), only pulmonary lesions and fibrosis but no tumors were induced (Smith et al., 1987).

In a study by Manville (1991b), groups of 107-109 Fischer 344 rats were intratracheally instilled with 2.0 mg of four different types of RCF: 1) kaolin RCF, 2) zirconia RCF, 3) high purity kaolin RCF, or 4) "after service" RCF (a kaolin-based ceramic fiber, containing 27% crystalline silica, which had previously been exposed to high temperatures). The dimensions of these fibers are assumed to be the same as those used in the inhalation study (Manville, 1991a). Positive controls were instilled with 0.66 mg suspension of chrysotile asbestos. Negative controls were instilled with vehicle (saline) alone. Preliminary results of this study show the induction of lung tumors (adenoma/carcinoma) by all four types of RCFs in the treated rats. The tumor incidences were: kaolin RCF: 6/109 (5.5%); zirconia RCF: 4/107 (3.7%); high purity kaolin: 4/109 (3.7%); and "after service" RCF: 7/108 (6.5%). In addition, pleural mesothelioma was present in 1 of 107 rats (0.9%) exposed to zirconia RCFs. The incidence of lung tumors in the positive control group (chrysotile asbestos) was 8/55 (14.5%). None of 118 negative control rats had any lung tumors.

Wagner et al. (1973) administered a single dose of 20 mg ceramic aluminum silicate fibers (0.5-1.0 μm in diameter, length unspecified) or Canadian SFA chrysotile fibers (two samples) to groups of 31-36 SPF Wistar rats (about twice as many males as females) via intrapleural injection. Animals were held until natural death. Pleural mesotheliomas were observed in 3/31 (9.7%) rats treated with ceramic aluminum silicate fibers. Mean survival time for this group was 736 days. The incidence of mesothelioma in the groups treated with the two samples of chrysotile fibers were: 21/32 (64%) and 23/36 (67%). Mean survival times for these groups were 639 and 568 days, respectively. In earlier experiments reported in the same study, no mesotheliomas were reported in negative (saline) controls: 0/48 rats had mesotheliomas in an earlier experiment in which the mean survival was 728 days and 0/32 rats had mesotheliomas in a second experiment in which the mean survival was 818 days.

II.A.4. Supporting Data for Carcinogenicity

There is ample evidence from epidemiologic and animal studies that exposure to asbestos causes, in addition to lung cancer and mesothelioma, excess rates of lung fibrosis (asbestosis) and pleural changes. Many of these non-neoplastic pulmonary and pleural changes (e.g., pleural plaques) have been useful markers and most diagnostic for asbestos exposure. Refractory ceramic fibers (RCFs) are similar to asbestos in fiber sizes and many of their physical properties (e.g., durability), which are critical factors for their pathogenicity. Although no human data are available regarding cancer from exposure to RCFs, a pulmonary morbidity study conducted on workers manufacturing RCFs and RCF products at five U.S. manufacturing facilities has shown an increased rate of pleural plaques among workers in the RCF industry (Lockey et al., 1991).

Inhalation studies in rats (Davis et al., 1984) and hamsters (Carborundum, 1990) also showed that aluminum silicate RCFs caused pulmonary and pleural fibrosis (in addition to lung tumors and mesothelioma).

II.B. Quantitative Estimate of Carcinogenic Risk from Oral Exposure

The available data are not appropriate for oral quantitation.

II.C. Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure

The available inhalation data (single dose) are not appropriate for quantitation.

II.D. EPA Documentation, Review, and Contacts (Carcinogenicity Assessment)

II.D.1. EPA Documentation

Source Document — U.S. EPA, 1988

The 1988 Health Hazard Assessment Document for Nonasbestos Fibers has received Agency and external review.

II.D.2. EPA Review (Carcinogenicity Assessment)

Agency Work Group Review — 03/31/1992

Verification Date — 03/31/1992

II.D.3. EPA Contacts (Carcinogenicity Assessment)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX) or hotline.iris@epa.gov (internet address).

III. [reserved]

IV. [reserved]

V. [reserved]

VI. Bibliography

Substance Name — Refractory ceramic fibers
CASRN — Not found

VI.A. Oral RfD References

None

VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

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Wagner, J.C., G. Berry and V. Timbrell. 1973. Mesotheliomata in rats after inoculation with asbestos and other minerals. *Br. J. Cancer.* 28: 173-185.

VII. Revision History

Substance Name — Refractory ceramic fibers

CASRN — Not found

Date	Section	Description
09/01/1992	II.	Carcinogenicity assessment on-line

VIII. Synonyms

Substance Name — Refractory ceramic fibers

CASRN — Not found

Last Revised — 09/01/1992

- Ceramic fibers
- Refractory ceramic fibers