TIMA INC.
ASSOCIATION OF MAN-MADE VITREOUS FIBER PRODUCERS

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Refractory Ceramic Fibers
Health and Safety Research Update
Animal Inhalation and Human Studies
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Health and Safety Research Studies

Dedication to Research and Safety

TIMA Inc. is the trade association of North American manufacturers of glass fiber, mineral wool, and refractory ceramic fibers (RCFs) used in products such as thermal insulation products. These fibers are also known as man-made vitreous fibers (MMVFs).

TIMA's mission is to help promote the safety of its industry products by sponsoring, conducting and monitoring medical/scientific research and disseminating the research results. TIMA member companies have invested more than $30 million in research projects with leading laboratories and universities in the United States and abroad.

TIMA-supported research involves a broad range of fiber studies including animal inhalation, human epidemiology, and industrial hygiene monitoring in order to develop a comprehensive health and safety evaluation of its industry's products.

The RCF Industry

RCF is one type of man-made vitreous fiber. It is synthetic, amorphous, and glassy in nature. RCF is created under controlled conditions from molten masses of raw materials such as naturally occurring kaolin clays, alumina/silica, or alumina/silica/zirconia. RCF is primarily used in industrial environments as thermal insulation to help control heat flow in high-temperature applications (up to 2,600 degrees Fahrenheit).

The U.S. RCF industry estimates 1989 annual sales of $125 million and has approximately 30,000 workers involved in the manufacturing, fabrication and installation of RCFs.

An Industry Initiative

In 1984, TIMA established a working group which outlined and subsequently initiated animal and human research studies designed to investigate the health and safety aspects of RCFs. These studies are being carried out with new, state-of-the-art protocols.

Included in this document are the most recent summaries, interim results and information from TIMA-sponsored RCF animal and human research studies. Additional research, other than the studies reported on here, is also being conducted by European manufacturers and by individual U.S. companies.

Animal Inhalation Research Study
24-Month Interim Results

Background

In June 1988, a two-year study was initiated to determine the chronic biological effects of inhaled refractory ceramic fibers (RCFs) in rats and hamsters. The research is being conducted at Research and Consulting Company, AG (RCC) in Geneva, Switzerland. The final results will be reported in 1991.

Preliminary Investigation

Following established scientific procedure, a preliminary investigation was conducted prior to the chronic study. The purpose of the preliminary investigation was to determine the maximum amount of material the animals could breathe (known as the "maximum tolerated dose") without developing acute effects that could shorten the animals' life spans, thus interfering with the two-year chronic study.

Methodology

Using the results of the preliminary investigations, groups of rats were then exposed to a maximum tolerated dose of 30 mg/m^3 (approximately 250 fibers per cc; fibers generally greater than 15 microns in length) of four different refractory ceramic fibers for six hours per day, five days per week. The following fibers were selected because they are considered to be most representative of the industry:

1) kaolin RCF
2) zirconia RCF
3) high-purity RCF
4) "after-service" RCF (a kaolin-based ceramic fiber that had previously been exposed to high temperatures).

Hamsters were exposed to only one type of RCF, (i.e., kaolin RCFs). Positive controls (chrysotile asbestos, 10 mg/m^3, approximately 5,000 fibers per cc; fibers generally less than 5 microns in length) and negative controls (filtered air) were included in both the rat and hamster studies.

Interim sacrifices to monitor the effects of these exposures were carried out on the study groups as follows:

Interim Sacrifice Schedule	Study Group
3 months	rat and hamster
6 months	rat and hamster
9 months	rat and hamster
12 months	rat and hamster
15 months	rat only
18 months	rat and hamster
24 months	rat only

Animal exposure was scheduled to be stopped after 18 months for the hamsters and after 24 months for the rats, and final sacrifices would occur when a 20 percent survival rate was reached.

Interim Results (18-month sacrifice) - Hamsters (Maximum Tolerated Dose)

Following are the results of the final sacrifice for the hamster study group:

- A total of 36 pleural mesotheliomas (a cancer affecting a membrane which lines the lungs) were observed in the 102 hamsters at risk which were exposed to kaolin RCFs. In addition, microscopic examination of the hamsters' lungs revealed fibrosis.

- A non-malignant mesothelial growth was found in the lining of the lungs (pleura) of one of the chrysotile asbestos-exposed hamsters. In addition, microscopic examination of the chrysotile asbestos-exposed hamster lungs revealed fibrosis.

- Negative-control hamsters (those exposed to filtered air) had no lung lesions.

Interim Results (24-month sacrifice) - Rats (Maximum Tolerated Dose)

Following are the latest available interim results for the rat study group:

- Through 24 months, sacrifices for interim pathological studies in rats have revealed two benign lung tumors, 7 lung carcinomas and 3 mesotheliomas in RCF-exposed animals. In addition, a thymic adenoma, thought to be spontaneous and one lung carcinoma were observed in rats exposed to chrysotile asbestos.

- Microscopic examination of the rats sacrificed after 24 months also revealed that exposure to kaolin RCF, zirconia RCF, high-purity RCF, "after-service" RCF, and chrysotile asbestos resulted in pulmonary fibrosis. There appeared to be little or no progression of lung fibrosis between 12 and 24 months.

- The lung fibrosis observed in the chrysotile asbestos-exposed group was qualitatively and quantitatively different from that produced by RCFs. While changes occurred at the same location, the deposition of collagen produced by chrysotile asbestos was more severe than that produced by the RCFs.

Summary

Final findings with hamsters (18 months) and interim findings with rats (24 months) demonstrate that RCFs have the potential to induce lung disease in animals breathing high concentrations (the maximum tolerated dose) of refractory ceramic fibers.

It should be emphasized that the 24-month results in rats are interim findings and final conclusions can not be made until the study is completed. It is important to note that test animals were exposed to an equivalent of 250 f/cc or approximately 200 to 300 times more RCFs than actual worker exposure. Manufacturing workplace exposure levels are generally below 1 fiber/cc. Finally, these studies are being carried out with new, state-of-the-art protocols.

(Please refer to the TIMA RCF Question and Answer Guide for additional information about this study.)

Next Steps

TIMA is also funding a dose-response study of kaolin RCF in rats which was begun in August 1989. This inhalation study is designed to determine whether lower chronic exposure levels have any disease-inducing activity.

There are four groups of animals included in the study. Three groups are being exposed to three different levels of kaolin RCF, and the fourth group is the air-breathing control.

In this lifetime study, the three groups of rats are exposed to approximately 150, 75, and 25 fibers/cc respectively (respirable fibers less than 3 microns in diameter and greater than 15 microns in length), for 6 hours per day, 5 days a week, for 24 months. Summaries of the findings of this study will be available after the final sacrifices which are expected to occur by the end of 1991. The final report will not be available until 1992.

(The interim findings of the Research and Consulting Company, AG Study have been reported to the Environmental Protection Agency (EPA) pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA).)

Question and Answer Guide
Animal Inhalation Research Study
Updated to Include 24-Month Interim Results

TIMA Inc. has developed the following Question and Answer guide to provide information on refractory ceramic fibers (RCFs) and the latest RCF research. These questions and answers address frequently discussed topics, but are not meant to replace the information contained in the individual Material Safety Data Sheets (MSDSs), labels, and other product literature produced by companies that manufacture RCFs.

1. What is TIMA Inc.?

TIMA Inc. is a non-profit trade association of North American manufacturers of glass fiber, mineral wool, and refractory ceramic fibers (also known as man-made vitreous fibers) used in thermal insulation products. Some TIMA member companies also manufacture other products made from man-made vitreous fibers, including acoustical ceiling tiles and panels.

2. What is refractory ceramic fiber (RCF)?

Refractory ceramic fiber is a man-made vitreous fiber. It is synthetic, amorphous, and glassy in nature. RCF is created under controlled conditions from molten masses of raw materials such as naturally occurring kaolin clays, alumina/silica, or alumina/silica/zirconia.

3. What is RCF used for?

RCF is primarily used in industrial environments as thermal insulation to help control heat flow in high-temperature applications (up to 2,600 degrees Fahrenheit).

Applications vary, but the most common uses include as oven and kiln wall liners, backup insulation to refractory brick, as soaking pit covers, and in annealing welds. The loose fiber is used as filler, as packing to fill voids and to seal expansion joints in furnaces and other heat resistance applications. Custom molded shapes have wide use in metal molding, as heating element supports, and in furnace combustion chamber liners.

4. Is RCF used outside of the workplace?

RCF is used in specialized applications in the automotive and appliance industry as high-temperature insulation (e.g., catalytic converters, oven wall and wood-burning stove seals). In these applications, RCF insulation is contained or encapsulated.

5. Is the general public exposed to RCF?

Because RCF is used primarily in industrial high-temperature applications, it would be unlikely for the general public to be exposed to RCF. When used in catalytic converters or some oven walls, the RCF insulation is encapsulated or securely contained within the walls or linings of the products, making any kind of exposure improbable.

6. **Which TIMA members manufacture RCF?**

RCF is manufactured throughout the world, primarily by The Carborundum Company, Premier Refractories, and Thermal Ceramics or their affiliates.

7. **What prompted RCF health research?**

There is an understandable concern about the safety of any materials which have the potential to give off particles or vapors which can be inhaled and/or ingested. For that reason, there have been and will continue to be many studies on RCF and other man-made vitreous products such as glass fiber and mineral wool.

8. **Why has TIMA chosen to make additional information available at this time?**

Interim results have been received from a TIMA-sponsored lifetime maximum-tolerated-dose animal inhalation study designed to determine the chronic biological effects of inhaled refractory ceramic fibers in rats and hamsters. The study is being conducted at Research and Consulting Company, AG (RCC) in Geneva, Switzerland. TIMA and its member companies are committed to making this information available to the public as soon as results are available.

The results of this study are also reported in accordance with Environmental Protection Agency regulations pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The final results of the study are expected in mid-1991. (For a more detailed discussion of this study, see the separate TIMA document, RCC-RCF Study.)

9. **What are the interim results of the Research and Consulting Company RCF Study?**

Interim findings, based on 18 and 24 months of animals breathing the maximum tolerated dose concentrations of refractory ceramic fibers, show that RCFs have the potential to induce lung disease in animals at those maximum levels.

10. **How do scientists evaluate these findings in animals with regard to the risk of cancer to human beings?**

While scientists agree that definitive evidence of carcinogenicity in humans is provided by epidemiological studies, indications of possible risk for human carcinogenicity may be provided by experimental animal studies as well. Since inhalation is the route of exposure for humans, animal inhalation studies are regarded by national and international regulatory and other agencies as most relevant to possible human risk.

However, the first Research and Consulting Company RCF study exposed animals to maximum tolerated doses -- administering the greatest dose possible without prematurely shortening the animals' lives. Animal tests are now underway to investigate the effects of lower doses of RCFs. TIMA began a multi-dose response study in 1989 to evaluate the effects of lower inhalation concentrations of RCFs and to identify a concentration

level which produces no effects in laboratory animals (known as a no-effect exposure level or NOEL).

11. Are RCFs safe?

TIMA members that produce RCFs believe they are safe to manufacture and use when recommended work practices are strictly followed as defined in their Material Safety Data Sheets (MSDSs) and other literature.

12. Have RCF research results been reviewed by any outside, independent agency?

Yes. The International Agency for Research on Cancer (IARC) reviewed all published information on man-made vitreous fibers in June 1987. IARC is a scientific institution of the World Health Organization and is devoted to research activity related to the prevention of human cancer. The conclusions of their working groups are disseminated to health authorities and the scientific community.

13. How did IARC classify RCFs?

Refractory ceramic fibers along with all man-made vitreous fibers were classified by IARC as Category 2B, except for continuous filament fiber, which was ranked as Category 3. It is important to note that IARC's classification of RCFs was not based on evidence of human carcinogenicity but rather on evidence pertaining only to animal carcinogenicity.

IARC provides the following classifications in regard to the carcinogenicity of substances:

Category 1:	Sufficient evidence of human carcinogenicity.
Category 2A:	Probably carcinogenic to humans.
Category 2B:	Possibly carcinogenic to humans.
Category 3:	Not classifiable as to human carcinogenicity.
Category 4:	Probably not carcinogenic to humans.

14. What other RCF research in animals is TIMA doing?

In August 1989, a dose-response study in rats was initiated at RCC in Geneva, Switzerland. The study is in the process of evaluating the effects of lower inhalation concentrations of RCF in order to identify a no-effect exposure level. This study will help refine more specific exposure guidelines and complements other on-going TIMA-supported studies.

15. Is TIMA conducting any studies dealing with RCF workers?

Other TIMA-sponsored RCF studies include a University of Cincinnati ongoing pulmonary health surveillance study of RCF workers; determination of the possible exposure levels of past workers and users and their subsequent health histories; and industrial hygiene surveys to determine the extent to which current workers and users may be exposed to respirable fibers.

16. Is RCF specifically regulated by any federal agency?

No. Currently there are no specific federal regulations regarding the manufacturing, handling, use, or disposal of RCFs.

17. Is RCF classified specifically as a hazardous waste?

No. Neither the fiber nor the waste generated by this product are currently classified or defined as hazardous by state or federal agencies in the U.S., unless contaminated in application.

18. Is there a recommended exposure level for RCFs?

The Occupational Safety and Health Administration (OSHA) has not instituted a specific recommended exposure level (known as permissible exposure limit or PEL) for refractory ceramic fibers.

The National Institute for Occupational Safety and Health, however, (NIOSH, 1977) has recommended that occupational exposure to all MMVFs be controlled so that no worker is exposed to an airborne concentration greater than 3 fibers per cubic centimeter (f/cc) and 5 mg/m^3. Various manufacturers have adopted recommended exposure levels (RELs). Consult manufacturers' Material Safety Data Sheets (MSDSs), labels or other literature for specific recommendations.

19. What are the typical exposure levels to RCF?

Based on industrial hygiene monitoring tests, manufacturing workplace exposure levels generally are below 1 fiber per cubic centimeter. Appropriate work safety practices such as respiratory protection and engineering controls should be provided where the potential exists for exposures higher than the manufacturer's recommended exposure levels during fabrication, installation or removal. Each TIMA member company which produces RCF has established recommended exposure levels and work safety practices. Specific information about each company's worker safety practices can be found in the MSDSs, labels, and other company literature.

20. Where can more information be obtained?

Anyone interested in more detailed information about topics covered in this Question and Answer Guide may contact:

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Pulmonary Morbidity Study of Workers
University of Cincinnati
Interim Results

Background

In 1987 an epidemiological study was started to evaluate the pulmonary health of current workers involved with manufacturing refractory ceramic fibers (RCFs) and/or RCF products. This study is being conducted by Drs. Lockey, Lemasters and Rice at the University of Cincinnati. The primary objective of this morbidity study is to determine if workers involved with RCF manufacturing are at increased risk for the development of adverse respiratory outcomes.

Methodology

During the period October 1987 through September 1989, more than 700 current workers at five RCF manufacturing facilities in the United States participated in this pulmonary morbidity study. Approximately 30% of the RCF exposed employees had between 10 and 20 years of exposure and 4% had greater than 20 years duration of exposure.

The program consisted of the following:

- Administration of an occupational history questionnaire;
- A modified American Thoracic Society (ATS) respiratory questionnaire;
- Spirometric testing to measure lung function; and
- Chest X-ray.

Industrial hygiene monitoring was conducted quarterly during the October 1987 - September 1989 period, with yearly updates of respiratory and occupational histories as well as lung function (spirometry). Every third year, the ATS questionnaire is administered and chest X-rays are conducted.

Exposure to RCF was characterized as production or non-production. Non-production workers were compared with 1) those production workers with ten years or less duration of exposure to RCF, and 2) those having greater than ten years duration of exposure to RCF, while adjusting for other risk factors.

Summary of Interim Results

- A cross-sectional analysis of the study population is nearing completion. The preliminary results suggest that duration of exposure within an RCF manufacturing facility may be associated with small, but not clinically significant, loss of lung function. Further analysis is needed to determine if this pattern persists. Although these small decrements are detected in the large population survey, further analysis is needed to determine if this pattern has any clinical relevance for an individual worker.

- Preliminary analyses of the chest X-rays appear to indicate a relationship between a long duration of employment in an RCF manufacturing facility and pleural plaques (shadows along the inside of the chest wall) found in X-rays of a small number (12) of workers. The investigators have indicated that additional review of the available clinical and previous work history data is underway to investigate the possibility of alternative explanations for this association. This is especially important in view of the small number of cases and the possibility of other occupational exposures.

Next Steps

This is the first morbidity study of its kind of U.S. workers involved in RCF manufacturing and reports on the results of a cross-sectional evaluation of currently employed RCF workers at five plants. It is intended that this study be expanded to include former employees and to establish a mortality registry. The investigators are now conducting additional research to determine how other factors such as prior employment history and past occupational exposures may contribute to the appropriate evaluation of results. Additional information on this study can be expected in late 1991.

Question and Answer Guide
Pulmonary Morbidity Study of Workers
University of Cincinnati

1. **What are the results of the University of Cincinnati human RCF study being conducted by Drs. Lockey, Lemasters and Rice?**

This ongoing research study is in the earliest stages. The information provided represents the initial analysis of the currently available data. Dr. Lockey has suggested that based on currently available data, duration of exposure within an RCF manufacturing facility may be associated with small, but not clinically significant, loss of lung function. Further analysis is needed to determine if this pattern persists. Although these small decrements are detected in the large population survey, further analysis is needed to determine if this pattern has any clinical relevance for an individual worker.

The investigators state that preliminary analyses of the chest X-rays appear to indicate a relationship between a long duration of employment in an RCF manufacturing facility and pleural plaques (shadows along the inside of the chest wall) found in X-rays of a small number (12) of workers. The investigators have indicated that additional review of the available clinical and previous work history data is underway to investigate the possibility of alternative explanations for this association. This is especially important in view of the small number of cases and the possibility of other occupational exposures.

The University of Cincinnati with funding from TIMA is conducting additional research to determine how other confounding factors such as prior employment history and past occupational exposures may contribute to the appropriate evaluation of results.

It is important to note that the higher worker exposure in these manufacturing facilities occurred at a time prior to the modernization of production facilities and the adoption of current work practice programs of TIMA member companies.

2. **What do these human research results mean to the health of RCF manufacturing employees?**

It is important to understand that this is the initial analysis of data from an ongoing research study. Further analysis of current as well as additional data will help determine if there is any implication for workers' health. As always, recommended work practices should be strictly followed as defined in the Material Safety Data Sheets (MSDSs) and other literature of TIMA members that produce RCFs.

3. Taken together, what is the relationship between the RCF animal research results and RCF human research results?

It is premature to determine whether there is any relationship at this time. It will be essential to complete other animal research, specifically the ongoing multi-dose study to be reported by mid-1992, and for the investigators to further analyze the animal and human data in order to understand the health and safety implications.

In the meantime, TIMA member companies continue their commitment to protecting the health, safety and welfare of employees and workers through appropriate work practices and prudent product stewardship of RCF.

4. Where can more information be obtained?

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Glossary of Selected Health and Science Terms

ACGIH. A professional organization, the American Conference of Governmental Industrial Hygienists.

Aerosol. Liquid droplets or solid particles, including fibers, dispersed in air. They are fine enough to remain dispersed for a period of time.

After-Service. A classification used to identify RCF product after it has been used at temperatures greater than 1800°F (Also see cristobalite.)

Amorphous. Non-crystalline in substance, glassy in character, having no molecular lattice structure.

Carcinogen. A substance or agent that has the ability or potential to induce or incite cancer.

CAS#. A Chemical Abstract Service number is the unique code assigned to a material to enable identification. Ceramic fiber is currently covered under the CAS# for glass, 65997-17-3.

Chrysotile Asbestos. Chrysotile is a type of asbestos that is a form of the serpentine minerals. After the asbestos is mined and milled, it is in the form of soft, flexible, silky, long fibers.

Cristobalite. A form of crystalline silica (see crystalline silica) generally considered and regulated as potentially more hazardous than quartz. Refractory ceramic fiber which has been in service at temperatures greater than 1800°F undergoes partial conversion to cristobalite.

Crystalline Silica. A naturally occurring mineral chemically defined as SiO_2. Quartz and cristobalite are both forms of crystalline silica. A common form of quartz is found in beach sand.

Cubic Centimeter. A metric system unit of volume, abbreviated cc and about the size of a small sugar cube, which is equivalent to one-thousandth of a liter (a metric unit of capacity). A liter is a little larger than a quart.

Devitrification. The process of change of a fiber from an amorphous, non-crystalline structure to a crystalline structure. It occurs when RCF fibers are used at temperatures greater than 1800°F.

Dose-Response. A relationship in which a change in amount, intensity, or duration of exposure is associated with a change -- either an increase or a decrease -- in risk of a specified outcome.

Durability. As it is used in these documents, it refers to the degree to which a substance resists dissolution in body fluids.

End User/End-Use Application. The final installer or installation for which a product was developed or designed.

Engineering Controls. Mechanical devices or means used to capture and contain ambient air contaminants.

Epidemiology. The study of the distribution and determinants of health-related states and events in populations (e.g., workers in a particular industry), and the application of this study to control of health problems.

ECFIA. A trade association, the European Ceramic Fiber Industry Association, of the manufacturers of refractory ceramic fiber products in Europe and the U.K.

Fibers Per Cubic Centimeter (f/cc). It is the number of fibers per cubic centimeter of air. (Also see cubic centimeter.)

Fiber. A slender, elongated filament with parallel sides, natural or synthetic, with a length of at least three times the width (i.e., an aspect ratio of at least 3:1). (Also see respirable fiber.)

Fibrosis. The formation of fibrous tissue by the excessive production of collagen. For example, it is the scarring of the lung that occurs when the natural defense mechanism attempts to reduce the insult caused by certain types of dust particles.

Fiber Exposure Monitoring. Determination of the concentration of airborne fiber found in the occupational environment using a sampling device consisting of a filter cassette and personal sampling pump. Analysis of the sample is done using optical microscopy and results are presented in f/cc (see fibers per cubic centimeter) of air. NIOSH (see NIOSH) has issued a standard method (No. 7400, Fiber in the Air) for this procedure.

Fume. Airborne, very finely divided solid particles formed during the heating of metal or plastic materials. Gases and vapors should not be referred to as fumes.

Gravimetric Exposure Monitoring. An industrial hygiene technique used to measure the amount of all airborne dust, not just fibers. The results are presented in milligrams per cubic meter (mg/m^3).

Hazard Communication Standard. A regulation, established by OSHA and published in the Code of Federal Regulations (29 CFR 1910.1200), that includes requirements for employers to:

1. Have health and safety information available for all materials used in their workplace, and
2. Train all workers in the safe methods for handling and working with these substances, plus other requirements.

IARC. The International Agency for Research on Cancer, an agency of the World Health Organization (WHO). One IARC program in particular evaluates the carcinogenic risk of chemicals to humans.

Implantation/Injection/Instillation. Exposure techniques used in animal experiments that artificially bypass the natural defense systems:

1. Intrapleural -- deposit material adjacent to the covering of the lung.
2. Intrachael -- deposit material into the windpipe (trachea) leading to the lung.
3. Intraperitoneal -- deposit material into the abdominal cavity.

Industrial Hygiene. The science dedicated to the recognition, evaluation and control of occupational health hazards.

Inhalation Studies. Controlled laboratory studies in which test animals are placed in a chamber into which known amounts of an airborne substance (the substance(s) of interest) are introduced. The animals breathe the substances for specific time periods, often from one to two years. The animals are followed closely to determine possible adverse effects.

Lesion. An abnormal change in structure of an organ or part, due to injury or disease.

Lung Burden. The amount of fiber or foreign substance retained in the lung, usually after prolonged exposure to the substance(s) of interest.

Macrophages. Any of the scavenger cells in the wall of blood vessels and connective tissue. In particular, alveolar macrophages ingest inhaled particulate matter in the lung.

Malignant Neoplasm. Cancerous disease capable of spreading (i.e., metastasizing) to other areas.

Man-Made Mineral Fibers (MMMF). A family of man-made, amorphous, glassy products, including fibrous glass, mineral wool (rock/slag) and refractory ceramic fibers. (Also referred to as man-made vitreous fibers which is the preferred term.)

Man-Made Vitreous Fibers (MMVF). A family of man-made, amorphous, glassy products, including fibrous glass, mineral wool (rock/slag) and refractory ceramic fibers. (Also referred to as man-made mineral fibers.)

Material Safety Data Sheet (MSDS). A document containing information about a product, including chemical and physical properties, and health and safety considerations. Manufacturers are required by OSHA (see Hazard Communication Standard) to prepare and distribute current and effective MSDSs to their customers.

Mesothelioma. A rare cancer which affects mesothelial tissue, the tissue covering the outside of the lung and other organs.

Milligrams Per Cubic Meter (mg/M^3 or mg/m^3). The weight of dust, in milligrams, per cubic meter of air sampled (see gravimetric exposure). A cubic meter is a metric unit of volume equal to a cube with edges of length one meter. It is slightly larger than a cubic yard. There are one million cubic centimeters in a cubic meter.

Micron. A metric unit of length that is one millionth of a meter, or one thousandth of a millimeter.

Milligram (mg). A metric unit of weight which is one-thousandth of a gram. An asprin typically weighs about 375 milligrams.

Morbidity Study. An epidemiologic study (see epidemiology) of the number of deaths and their causes in an identified population.

Maximum Tolerated Dose (MTD). That dose which, when given for the duration of the chronic study as the highest dose, will not shorten the treated animals' longevity from any toxic effects other than the induction of neoplasms. The MTD should not cause morphological evidence of toxicity of a severity that would interfere with the interpretation of the study. ("Report of NTP Ad Hoc Panel on Carcinogen Testing and Evaluation," U.S. Department of Health and Human Services Publication, August 1984, p.126.)

NIOSH. The National Institute for Occupational Safety and Health, it is a branch of the Department of Health and Human Services. The responsibility of NIOSH includes the development of sampling and analytical methods for industrial hygiene monitoring, and the recommendation of workplace exposure limits.

NOEL. An abbreviation for "no-effect exposure level," this term is applied to a concentration level of a substance below which no effects in laboratory animals is observed.

Non-Malignant Neoplasm. A tumor that is not capable of spreading (see Malignant Neoplasm).

Nuisance Dust. Dust that does not contain any specifically regulated substances.

Occupational Exposure. The exposure encountered by a worker while producing, using (e.g., fabricating) or otherwise working with (e.g., installing or removing) a product.

OSHA. The Occupational Safety & Health Administration, it is an agency of the U.S. Department of Labor, that is charged with the responsibility for ensuring the safety and health of American workers through development and enforcement of standards and regulations.

Parenchyma. The essential or functional elements of an organ. Of special interest is the lung parenchyma, which, if excessively scarred, interferes with the ability to breathe.

Permissible Exposure Limit (PEL). The maximum level of a substance to which an employee may be exposed during any eight-hour shift of a 40-hour week. PELs are established by OSHA and are enforceable by law. No specific PEL has been set for refractory ceramic fiber.

Pleura. The delicate serous membrane that lines the lungs. It is folded back over to form a double lining.

Pleural Cavity. The cavity is the potential space between the two layers of the pleura. (See pleura.)

Pleural Plaque. Usually small irregular spots or shadows on the lining of the lungs as detected by X-rays or other non-invasive scanning procedures.

Positive Control. The inclusion of a substance in test procedures which had been shown previously to induce disease in animals of the same type under similar test conditions. This control is usually included to validate the test model by showing that animals of the present study are susceptible to disease induction.

Prospective Study. The essential feature of prospective epidemiological studies is that the researcher gathers information and records events moving forward in time. (Also see Epidemiology and Retrospective Study.)

Radiology. The branch of medical science dealing with the use of nuclear energy (e.g., X-rays and "CAT" scans) in the diagnosis and treatment of disease.

Refractory Ceramic Fiber (RCF). One member of a family of products frequently referred to collectively as man-made vitreous fibers because of their synthetic, amorphous, glassy nature. RCF is produced from molten masses of raw material under highly controlled conditions at approximately 3000°F.

Respirable Dust. The fraction of airborne dust that can penetrate deeply into the lower lung regions.

Respirable Fiber. A fiber that is part of the respirable fraction of airborne dust. Generally, a respirable fiber of airborne dust. Generally, a respirable fiber is one that is less than three microns in diameter. (Also see respirable dust and fiber.)

Retrospective Study. The essential feature of retrospective epidemiological studies is that the research designs look at information and events of the past. (Also see Epidemiology and Prospective Study.)

Sacrifice. A scientific term used to describe the process of terminating the life of an animal involved in an ongoing long-term study to evaluate the effects of the test article.

Silicosis. A lung disease caused by excessive exposure to respirable crystalline silica dust.

Spontaneous. An event occurring with no known cause.

Statistically Significant. A phrase used to describe an event that was possible, but was unlikely to have occurred by chance alone.

Threshold Limit Value (TLV). It is the Time Weighted Average (TWA) for a normal 8-hour work shift and a 40-hour work week, below which is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect - established as guidelines by the ACGIH (see American Conference of Governmental Industrial Hygenists). No specific TLV has been set for RCF. (Also see Permissible Exposure Limit.)

Thymic Adenoma. A benign tumor in the epithelium (covering) of the thymus.

TIMA Inc. The national trade association of North American manufacturers of glass fiber, mineral wool, and refractory ceramic fibers (also known as man-made vitreous fibers) used in thermal insulation products. Some TIMA member companies also manufacture other products made from man-made vitreous fibers, including acoustical ceiling tiles and panels.

Time Weighted Average (TWA). The concentration of a contaminant which has been weighted for the time duration of the sample - high exposures of short sample duration do not "weigh" as heavily in the calculation as do moderate levels for extended periods. Most exposure limits are referenced to eight-hour TWA sample results.

Total Dust. All airborne dust found in an environment.

Tumorigenic. The ability to induce tumors.

Vitreous. See Refractory Ceramic Fibers.