TALC

First Draft

October 1978

By: Center for Occupational and Environmental
Safety and Health

Prepared for:

Division of Criteria Documentation
and Standards Development
National Institute for Occupational
Safety and Health

SRI Project No. 6455

SRI International
1611 North Kent Street
Arlington, Virginia 22209

1611 N. Kent Street • Arlington, Virginia 22209
(703) 524-2053 • Cable: SRI INTL WDC

PLAINTIFF'S EXHIBIT
WCD-159

TALC FIRST DRAFT

I. RECOMMENDATIONS FOR A TALC STANDARD

NIOSH recommends that employee exposure to talc in the workplace be controlled by adherence to the following sections. The standard is designed to protect the health and provide for the safety of employees for up to a 10-hour workshift, 40-hour workweek, over a working lifetime. Compliance with all sections of the standard should prevent adverse effects of talc on the health of employees and provide for their safety. The standard is measurable by techniques that are valid, reproducible, and available to industry and government agencies. Sufficient technology exists to permit compliance with the recommended standard. The employer should record the recommended workplace limits as the upper boundary for exposure and make every effort to keep the exposure as low is technically feasible. The criteria and recommended standard will be subject to review and revision as necessary.

The term "talc" refers to material containing hydrous magnesium silicate ($Mg_3Si_4O_{10}(OH)_2$). Nonasbestiform talc, nonfibrous talc, soapstone or French chalk are terms frequently encountered in the literature and sometimes used interchangeably to describe talc. Talc is a natural mineral with a crystalline structure consisting of a brucite sheet ($Mg(OH)_2$) sandwiched between two silica sheets and possesses such physical characteristics as softness, slipperiness, and hydrophobicity. Exposure to talc may occur during the mining, milling, processing, distribution, storage and use of talc. "Occupational exposure" to talc is defined as exposure to airborne talc at a

WCD 001038

concentration above one-half the recommended environmental limit for talc (see Section II). The recommended environmental limit is based on data indicating that talc may cause both transient and permanent lung damage. Exposure to talc at lower concentrations will not require adherence to the following sections except 2(a), 3(a), 6(b-e), 7, and 8(a).

Talc is sometimes found mixed with free silica and asbestos or asbestiform minerals such as tremolite, anthophyllite or chrysotile. When this is the case, the employer should also comply with the standards proposed by NIOSH for these minerals. These standards can be found in the NIOSH criteria documents for a recommended standard for crystalline silica and the original and revised criteria documents for asbestos. If exposure to other materials also occurs, provisions of any applicable standards for the other materials shall also be followed. The following sections are for control of exposure to talc free of free silica, asbestos, or asbestiform minerals.

Section I - Environmental (Workplace Air)

(a) Concentration

Occupational exposure to talc shall be controlled so that employees are not exposed to talc at a concentration greater than 0.1 milligrams per cubic meter of air (0.1 mg/cu m) determined as a time-weighted average (TWA) concentration for up to a 10-hour workshift in a 40-hour workweek.

WCD 001039

precision, and sensitivity.

Section 2 - Medical

Medical surveillance shall be made available as outlined below to all employees occupationally exposed to talc.

(a) Preplacement or initial examinations shall include at least:

(1) Comprehensive medical histories with special emphasis directed towards identifying existing disorders of the respiratory system, heart, and lungs and comprehensive work histories to determine previous occupational exposure to potential respiratory and lung irritants and pulmonary carcinogens and smoking histories.

(2) Physical examination giving particular attention to the upper and lower respiratory tract, heart, and lungs. Respiratory tract and lung examinations should pay particular attention to any pretumorous and tumorous lesions.

(3) Specific clinical tests, including at least a 35- x 42-cm posteroanterior and lateral chest roentgenogram and pulmonary function tests including forced vital capacity (FVC), forced expiratory volume in 1 second (FEV 1), and sputum cytology.

(4) A judgment of the employee's ability to use positive and negative pressure respirators.

(b) Periodic examinations shall be made available at least annually. These examinations shall include at least:

(1) Interim medical and work histories.

WCD 001040

(2) Physical examination and clinical tests as outlined in (a)(2) and (a)(3) of this section except that bacteriographic examinations shall be made available for workers occupationally exposed to talc at average concentrations greater than 0.1 mg/cu m annually and for workers occupationally exposed at less than 0.1 mg/cu m every 3 years.

(c) During examinations, applicants or employees found to have medical conditions, eg, respiratory impairment or lung injury, that might be directly or indirectly be aggravated by exposure to talc shall be counseled on the increased risk of impairment of their health from working with this substance. Applicants or employees should also be counseled on the increased risk from smoking during talc exposure.

(d) In the event of contamination of wounds or eyes by talc, the contaminated area should be promptly and thoroughly cleaned and appropriately dressed to prevent further contamination.

(e) Pertinent medical records shall be maintained for all employees occupationally exposed to talc. Such records shall be kept for at least 20 years after termination of employment. These records shall be made available to the designated medical representatives of the Secretary of Health, Education, and Welfare, of the Secretary of Labor, of the employer, and of the employee or former employee.

Section 3 - Labeling and Posting

All labels and warning signs shall be printed both in English and in the predominant language of non-English-reading workers. Workers unable to read

WCD 001041

the labels and posted signs provided shall be informed verbally about
163 hazardous areas and of the instructions printed on the labels and signs.
168 (a) Labeling
171 Shipping and storage containers of talc shall bear labels describing the
172 hazardous, major ingredients, chemical name, and information on the possible
173 effects on human health as follows:

176 TALC
177 MAY CAUSE DELAYED LUNG INJURY (Talcosis)

181 Use only with adequate ventilation.
182 Avoid breathing dust.
183 Avoid contact with eyes or open skin wounds.
184 Consult a physician if lung symptoms develop.

187 (b) Posting
190 (1) The following warning sign shall be posted in readily visible
191 locations at or near all entrances to areas where talc or talc-containing
192 materials are produced, handled, or stored.

199 TALC
196 MAY CAUSE DELAYED LUNG INJURY (Talcosis)

199 Use only with adequate ventilation.
200 Avoid breathing dust.
201 Avoid contact with eyes or open skin wounds.

WCD 001042

(3) If respirators are required in accordance with Section 4, for protection from talc, the following statement shall be added to the sign required in Section 3(b):

RESPIRATORY PROTECTION REQUIRED IN THIS AREA

Section 4 - Personal Protective Clothing and Equipment

Engineering controls shall be used when needed to keep the concentration of airborne talc at or below the recommended environmental limit specified in Section 1(a).

(a) Respiratory Protection

(1) The use of respirators to comply with the permissible exposure limits is permitted during installation and testing of engineering controls, during the time necessary to install or test the required engineering controls, during performance of nonroutine maintenance or repair, and during emergencies.

(2) When a respirator is permitted or required it shall be selected and used in accordance with the following requirements:

(A) To determine the type of respirator to be used the employer shall measure the concentration of airborne talc in the workplace initially and thereafter whenever control, process, operation, or worksite changes occur that are likely to increase the concentration of talc in the air of the workplace.

(B) The respirator shall be selected in accordance with the

WCD 001043

specifications in Table I-1 and shall be those approved by NIOSH or the Mine Safety and Health Administration (MSHA) as specified in 30 CFR 11.

(C) The employer shall establish and enforce a respiratory protection program meeting the requirements of 29 CFR 1910.134, and shall ensure that employees use required respiratory protective equipment.

(D) Respirators specified for use in higher concentrations of talc may be used in atmospheres with lower concentrations.

(E) The employer shall ensure that respirators are adequately cleaned, maintained, and stored in a dust free condition and that employees are properly instructed and drilled at least annually in the proper use, fit, and testing for leakage of respirators assigned to them.

(F) Respirators shall be kept in locations easily accessible to employees.

WCD 001044

TALC FIRST DRAFT
TABLE I-1

RESPIRATOR SELECTION GUIDE FOR TALC

Respirable Dust Concentration	Respirator Type Approved Under Provision of 30 CFR 11
Less than or equal to 0.5 mg/cu m	Single use or quarter-mask dust respirator
Less than or equal to 1 mg/cu m	(1) Half-mask dust respirator (2) Supplied air respirator with half-mask facepiece operated in demand mode with belt mounted demand regulator
Less than or equal to 5 mg/cu m	(1) Full facepiece high efficiency dust respirator (2) Full facepiece supplied air respirator operated in demand mode with belt mounted demand regulator or self-contained breathing apparatus with full facepiece operated in demand mode
Less than or equal to 100 mg/cu m	(1) Powered air purifying respirator with a full facepiece and high efficiency filter (2) Supplied air respirator with half-mask or full facepiece operated in pressure demand mode or supplied air respirator with half-mask, full facepiece, hood, or helmet operated in continuous flow mode.
Greater than 100 mg/cu m or entry into areas of unknown	(1) Self-contained breathing apparatus with full face-

WCD 001045

DALC FIRST DRAFT

air concentration
- pieces operated in pressure-
- demand or other positive
- pressure mode
- (42: Type C combination supplied-
- air respirator with full
- facepiece operated in
- pressure-demand mode and
- with auxiliary self-
- contained air supply

(b) Protective Clothing

(1) The employer shall ensure that open wounds on employees are covered to prevent contamination by talc through the use of appropriate bandages or dressings and appropriate work clothing.

(c) Eye Protection

The employer shall provide chemical safety goggles to employees experiencing eye irritation during exposure. Eye protection devices shall be selected, used, and maintained in accordance with CFR 1910.133.

Section 5 - Informing Employees of Hazards from Talc

(a) In addition to the medical counseling required in Section 2(c), each employee assigned to work in an area where occupational exposure to talc may occur shall be informed orally and in writing, by personnel qualified by training or experience, of the hazards and relevant symptoms of exposure to talc. Workers shall be advised that exposure to talc may cause transient or permanent lung disease or granuloma. The instructional program shall include a description of the medical surveillance procedures and of the advantages to the employee of participating in this program. The employer shall also ensure that each employee is informed of proper conditions and precautions for the protection, handling, and use of talc. This information shall be given to employees at the beginning of employment and at least annually thereafter. Employees shall also be instructed on their responsibilities for following proper work practices and sanitation procedures to help protect the health and provide for the safety of themselves and of fellow employees.

WCD 001047

(b) The employer shall institute a continuing education program, conducted by persons qualified by experience or training, to ensure that all employees have current knowledge of job hazards, proper maintenance and cleanup methods, and proper respirator use. Employees shall be provided with up-to-date information whenever there is a process change. The information in the Material Safety Data Sheet (Appendix III), shall be provided to workers and reviewed with them by qualified personnel, and shall be posted in locations readily accessible to employees at all places of employment where exposure to talc may occur.

(c) Required information shall be recorded on the "Material Safety Data Sheet" shown in Appendix III or on a similar form approved by the Occupational Safety and Health Administration, US Department of Labor.

Section 6 - Work Practices

(a) Control of Airborne Talc

Engineering controls, such as process enclosure and local exhaust ventilation, shall be used when needed to keep exposures to airborne talc dust at or below the recommended environmental limit. Ventilation systems shall be designed to prevent the accumulation or recirculation of talc in the workplace environment and to effectively remove it from the breathing zones of employees. In addition to effective local exhaust ventilation, maintenance of a slight negative pressure in all enclosed systems that handle dry talc may be needed so that when a leak develops, talc is contained within the system. Exhaust ventilation systems discharging to the outside air shall conform to

WCD 001048

applicable local, state, and Federal air pollution regulations. Contaminated exhaust air shall not be recirculated into the workplace. Ventilation systems should be inspected monthly and shall receive regular preventive maintenance and cleaning to ensure their continuing effectiveness and maintenance of design airflows. Airflow indicators, eg, oil or water manometers, should be used for continuous monitoring of the airflow.

(b) Control of Spills and Leaks

The employer shall ensure that only personnel properly trained in the emergency procedures and adequately protected against the attendant hazards shall be responsible for shutting off sources of talc, cleaning up spills, and repairing leaks. Dry sweeping should be avoided. Cleanups shall be performed by vacuuming.

(c) Handling and Storage

Direct contact of open skin wounds with talc should be avoided. Care should be exercised in handling talc to minimize spills. Talc should be stored in leakproof containers.

(d) Waste Disposal

Waste material contaminated with talc shall be disposed of in a manner that does not expose employees at concentrations above the recommended environmental limit. The disposal method must conform to applicable local, state, and Federal regulations and must not constitute a hazard to the surrounding population or environment.

(e) Confined Spaces

(1) Entry into confined spaces, such as tanks, dust collectors,

WCD 001046

process vessels, and tunnels, shall be controlled by a permit system. Permits issued by an authorized representative of the employer shall certify that preparation of the confined space, precautionary measures, and personal protective equipment are adequate and that prescribed procedures will be followed.

(2) Confined spaces shall be ventilated while work is in progress to keep the concentrations of talc and other air contaminants below the workplace environmental limit and to assure an adequate supply of oxygen. Air from the confined spaces shall be discharged away from any work areas. When ventilation cannot keep the concentrations of talc and other air contaminants below the recommended environmental limit, respiratory protective equipment shall be used in accordance with the provisions of Table I-1.

(3) Any employee entering confined spaces where the concentration of talc may exceed the recommended environmental limit or where other air contaminants are excessive or where oxygen is deficient shall wear appropriate respiratory protection, a suitable harness, and a lifeline tended outside the space by another employee also equipped with the necessary protective equipment. The two workers shall be in constant communication by some appropriate means and shall be under the surveillance of a third person equipped to take any action to rescue them if necessary.

(4) The employer shall require that only properly trained and authorized employees be permitted to enter work areas.

Section 7 - Sanitation Practices

WCD 001050

(e) Eating, preparing, storing, or the dispensing of food (including vending machines) shall be prohibited in all work areas where exposures to talc may occur.

To prevent contamination and to maintain good hygienic practices employees who handle talc or who work in an area where they are exposed to talc shall be instructed to wash their hands with soap or skin cleaners and water before using toilet facilities, drinking, eating, or smoking and to shower or bathe using soap or other skin cleansers at the end of each workshift before leaving the work premises.

(d) The employer shall provide change rooms equipped with shower facilities, and separate storage facilities for street clothes and for work clothing and equipment. The change rooms shall be in a nonexposure area.

Section 8 - Monitoring and Recordkeeping

(a) Industrial Hygiene Surveys

Each employer who processes or uses talc shall determine by an industrial hygiene survey if occupational exposure has or may occur. Surveys shall be repeated at least annually and within 30 days of any process change likely to result in an increase in the concentrations of airborne talc. Records of these surveys, including the basis for any conclusion that the concentrations of talc do not exceed the recommended environmental limit, shall be retained for at least 30 years.

(b) Personal Monitoring

If there is occupational exposure to talc, a program of personal

WCD 001051

monitoring shall be instituted to measure or permit calculation of the
539 exposures of all employees.

542 (1) Each operation in each work area shall be sampled at
543 least once every 6 months.

545 (2) In all personal monitoring, samples representative of the
546 breathing zones of the employees shall be collected.

549 (3) For each determination, a sufficient number of samples
550 shall be taken to characterize the employees' exposures during each workshift.
552 Variations in work and production schedules and in employees' locations and
553 job functions shall be considered in choosing sampling times, locations, and
554 frequencies.

556 (4) If an employee is found to be exposed to talc in excess
557 of the recommended environmental limit, control measures shall be initiated
558 promptly, and the employee shall be notified of the extent of the exposure and
560 of the control measures being implemented. When they are found to effectively
561 reduce the employee's exposure to the TWA limit or below, confirmed by two
562 consecutive determinations at least 1 week apart, routine monitoring may then
563 be resumed.

566 (c) Recordkeeping

569 Records of workplace environmental monitoring shall be kept for at least
570 30 years after the employee(s) last exposure to talc. These records shall
571 include the date and times of measurements, job function and location of the
572 employee within the worksite, methods of sampling and analysis used, types of
573 respiratory protection in use at the time of sampling, TWA concentrations

WCD 001052

found, and identification of the exposed employee(s). Employees shall be able to obtain information on their own workplace environment exposures.

Pertinent medical records shall be retained by the employer for 30 years after the last occupational exposure to talc. Records of environmental exposures applicable to an employee should be included in medical records. These medical records shall be made available to the designated medical representatives of the Secretary of Labor, of the Secretary of Health, Education, and Welfare, of the employer, and of the employee or former employee.

WCD 001053

II. INTRODUCTION

This report presents the criteria and the recommended standard based therein that were prepared to meet the need for preventive impairment of health from workplace exposure to talc. The criteria document fulfills the responsibility of the Secretary of Health, Education, and Welfare under Section 20(a)(3) of the Occupational Safety and Health Act of 1970 to "develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels...at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."

After reviewing data and consulting with others, NIOSH formulated a system for the development of criteria on which standards can be established to protect the health and provide for the safety of employees exposed to hazardous chemical and physical agents. Criteria for a recommended standard should enable management and labor to develop better engineering controls resulting in more healthful work environments, and simply complying with the recommended standard should not be regarded as the final goal.

These criteria for a recommended standard for talc are part of a continuing series of criteria developed by NIOSH. The recommended standard applies only to workplace exposure to talc generated by the processing, handling, use, or storage of talc. The standard is not designed for the

WCD 001054

population-at-large, and any extrapolation beyond workplace exposures is not warranted. The standard is intended to: (1) protect against the possible development of cancer and other health effects such as pulmonary lesions and nonpulmonary granulomas associated with occupational exposure to talc, (2) reduce eye and respiratory tract irritation, (3) be measurable by techniques that are valid, reproducible, and available to industry and government agencies, and (4) be attainable with existing technology.

Talc is marketed in a powder form, and the powder varies in particle size from very coarse to extremely fine. It is used in a variety of products including paint, ceramic, paper, rubber plastics as an extender, filler, or surface agent. In addition talc is widely used in cosmetic products. Workers' exposure to talc dust occurs during mining, milling (processing), handling, distribution, use, or storage of talc.

The available evidence indicates that workers occupationally exposed to talc may develop pulmonary lesions and nonpulmonary granulomas. Because talc is sometimes found mixed with asbestos or asbestiform minerals such as tremolite, anthophyllite, actinolite, or chrysotile, and free silica whose effects on human health are extensively documented in NIOSH criteria documents for a recommended standard for crystalline silica and in the original and revised criteria documents for asbestos, research is needed to adequately characterize talc deposits. More toxicologic data is needed concerning the health effects of relatively pure talc and talc with its associated minerals on the pulmonary and other physiologic systems such as the gastrointestinal, liver, and cardiovascular system. Such studies should also examine the

WCD 001055

clearance of talc administered through the oral and inhalation routes.

Epidemiologic studies of occupationally exposed people, experimental inhalation exposure, and studies of the carcinogenic potential of relatively pure talc are needed. Studies are also needed to investigate the possible mutagenic, teratogenic, and reproductive effects of talc. Further research is needed to determine possible synergistic effects produced by talc and its associated minerals--particularly chlorite, dolomite, magnesite, brucite and the trace metals.

WCD 001056

III. BIOLOGIC EFFECTS OF EXPOSURE

Pure talc is a hydrous magnesium silicate with the formula $Mg_3Si_4O_{10}(OH)_2$ with a theoretical composition of 31.7% MgO, 63.5% SiO_2, and 4.8% H_2O [1]. Commercially, the term talc refers to a mineral mixture meeting certain physical properties such as softness, slipperiness, and hydrophobicity [2]. Usually, but not always, such mineral mixtures contain talc as the major constituent.

Talc rocks are primarily formed by two complex geological processes [2,3]. They may evolve from the hydrothermal alteration of magnesium- and silica-rich ultramafic rocks under low to moderate temperatures and pressures. Anthophyllite ($(Fe,Mg)_7Si_8O_{22}(OH)_2$ and chrysotile ($Mg_3Si_2O_5(OH)_4$) may also be formed during this process. Talc rocks may also be formed from thermal metamorphosis of a carbonate rock such as dolomite, $CaMg(CO_3)_2$, with the introduction of silica. Through this process, tremolite, $Ca_2Mg_5Si_8O_{22}(OH)_2$, may also be formed. Thus, talc rock is usually a mixture of minerals that may vary widely with respect to composition. The minerals found within talc rock may occur as macroscopic nodules, as microscopic intergrowths with talc, or even as discrete zones within or adjacent to talc [2]. Table III-1 is a list of minerals that commonly occur in talc deposits.

Talc crystal consists of a brucite sheet ($Mg(OH)_2$) sandwiched between two silica sheets, forming layers that are indefinitely superimposed [4]. The adjacent layers are held together by weak van der Waal's forces, contributing

WCD 001057

to the slippery property when these layers slide across one another. The
698 crystal structure of talc is lamellar and thus does not easily form fibers
699 [5].

WCD 001058

TABLE II

COMPOSITION OF TALC MINED

Location	Mineral Composition and Impurities
Alabama	Principally talc with minor chlorite, traces of magnesite, quartz .
Arkansas	Talc mixed with dolomite, magesite and chlorite, minor quartz and calcite
California	Principally talc and tremolite with minor forsterite, serpentine, and carbonates Impurities are chlorite, quartz, phlogopite, pyrite, and iron oxide
Georgia	Talc with minor magnetite, carbonates Impurities are pyrite, chlorite, quartz, feldspar, actinolite, and sericite
Montana	Essentially talc with minor impurities such as chlorite, graphite, dolomite
New York	Proportion of tremolite, anthophyllite, talc, and serpentine varies widely, any may predominate, but tremolite rock is most common Impurities are quartz, carbonate, diopside, manganese, and iron oxides
North Carolina	Principally talc, traces of chlorite, dolomite, quartz and tremolite
Texas	Essentially talc Impurities are various amounts of quartz, carbonate, and organic material
Vermont	Essentially talc with minor magnetite, chlorite, and sulfides

WCD 001059

IN THE UNITED STATES

Commercial Use
Rubber paint, textiles and cosmetics
Rubber insecticides, wall tile
Rubber, pottery, paint, ceramics, paper, textiles, steatite, pharmaceuticals
Crayons, paint, rubber, roofing, insecticides, lubricants, foundry facings, cosmetics
Cosmetics, steatite, paints, paper, ceramics
Largely ceramics and paint, also rubber, plastics, insecticides, and foundry facings
Cosmetics, steatite, pharmaceuticals, rubber and paint
Chiefly wall tile; also insecticides
Paper, rubber, textiles, paint, roofing, crayons facings

? Not so

TALC FINAL DRAFT
TABLE III-1

MINERALS THAT COMMONLY OCCUR IN TALC DEPOSITS*

Mineral	Other Names	Formula	Crystal Morphology
Talc	French chalk Soapstone Steatite	3MgO 4SiO3 H2O	Lamellar
Tremolite	Amphibole	Ca2Mg5(OH)2Si8O22 or CaO·5MgO·8SiO2·H2O, FeO when contaminated with iron	Columnar
Anthophyllite	"	(MgFe)7Si8O22(OH)2	"
Chrysotile	Serpentine	3MgO·2SiO2·2H2O may contain iron or aluminum	"
Silica	Quartz	SiO2	"
Chlorite	Penninite	(Mg,Fe)5Al(AlSi3)O10(OH)8	
Calcite	Carbonate	CaCO3	
Dolomite	"	CaCO3	
Magnesite	"	MgCO3	
Mica	Phlogopite	K2(Mg,Fe)6(Si6Al2)O20(OH)4	

*Adapted from [2] and [5]

WCD 001060

Crude talc ranges in color from white to green and brown, depending on the composition [1]. After being ground to powder, all pure talc is white. Talc is inert in most chemical reagents, but it is soluble in hot concentrated phosphoric acid.

As mentioned above, talc rock is a mixture of minerals usually having talc as a major constituent. The associated minerals help to modify the physical properties of the mineral. The softness of talc mineral for example, is determined to a large extent by the associated minerals that may be present. The differences in physical properties of talc minerals make a wide range of commercial applications possible. Talc of high purity (>90% talc) is desirable for cosmetic and pharmaceutical use, and tremolitic talc is ideal for ceramic applications [1].

Tremolite and anthophyllite are among the minerals that have been found in talc deposits and in talc sold commercially. The crystal structures of tremolite and anthophyllite is columnar and may easily form fibers [5]. NIOSH has classified tremolite and anthophyllite as asbestos minerals along with amosite, actinolite and chrysotile. Pulmonary lesions such as pneumoconiosis and lung cancer have been associated with exposure to these minerals and NIOSH has reviewed the literature regarding these minerals in the documents, Criteria for a Recommended Standard ... Occupational Exposure to Asbestos and Revised Recommended Asbestos Standard. The OSHA asbestos standard will apply to talc containing asbestos.

Free silica has also been found in talc deposits and in talc sold commercially. The health effects of free silica, primarily silicosis, have

WCD 001061

also been extensively documented and are reviewed in the NIOSH document,
Criteria for a Recommended Standard--Occupational Exposure to Crystalline
Silica. The OSHA standard on free silica will apply for talc containing free
silica.

Although this document will address the exposure of workers to talc and it's associated minerals, or that which is commercially termed talc, the recommended standard will be based on talc not found to contain asbestos or free silica. Within this document the terms "nonfibrous talc" or "nonasbestiform talc" will refer to talc that does not contain asbestos minerals such as tremolite and anthophyllite. The terms "fibrous talc" or "asbestiform talc" will refer to talc that occurs with asbestos minerals.

The terms "industrial grade talc" and "technical talc" will be used to designate the generic product sold as talc commercially. Unless otherwise specified, the composition of these products are not known.

The terms "cosmetic talc" and "pharmaceutical talc" will be used to describe talc that is marketed for cosmetic or pharmaceutical uses and which does not contain free silica or asbestos, having undergone purification processes, such as flotation. A standard was proposed by the US Food and Drug Administration (FDA) in 1975 to require cosmetic talc to meet certain specifications, such as the absence of free silica and asbestos, before reaching the marketplace.

Extent of Exposure

Between 1965 and 1974, the total annual production of talc in the United

WCD 001062

States was approximately 1,290,000 tons. Production of talc minerals
815 increased between 1968 and 1972 at an average rate of 3.2%, and this growth
816 rate is expected to continue through 1980 (6).

819 Despite its varying chemical composition, talc is used as an extender,
820 filler, and versatile component in many industrial products. Approximately
821 70% of talc produced is used in industries manufacturing paint, ceramics,
822 rubber, roofing materials, and paper. The rest of the talc (usually over 99%
823 pure) is used in cosmetics, pharmaceutical, and food industries (6). In food
824 industries, talc is used for animal dusting, candy molding, and polishing of
825 peanuts and rice. Talc is also found in chalks and crayons, insecticides,
827 foundry facings, textiles, white shoe cleaners, pigments, dusting powders,
828 soap fillers, and lubricants. Worker exposure to talc dust is greatest when
829 talc is transferred, added to, or mixed on products and during accidental
831 rupture of bags or failure of engineering controls in the process in milling
832 plants during crushing, separation, bagging, loading, and end-application
833 operations.

835 Geologic processes determine the composition of talc and, consequently,
836 dictate to a large extent the end use of the talc (see Table III-2).
837 Therefore, talc mining and milling processes often do not need to greatly
838 alter the composition of talc mineral that is mined but rather produce a talc
840 product having desired physical properties, primarily particle size. As a
842 result, talc workers in mining, milling, and end application industries may be
843 exposed to a mixture of mineral dust rather than to only pure talc. NIOSH
845 estimates that, in 1977, approximately 1.7 million workers were occupationally

WCD 001063

exposed to various forms of talc in the mining, milling, and end-application
847 operations. This document will be concerned mainly with the health and safety
848 of workers exposed to talc in the milling and end-application operations.
849 Employees entered in talc mining operations will be covered by the safety
850 procedures and health regulations promulgated and enforced by the Mine Safety
851 and Health Administration (MSHA) of the US Department of Labor.

WCD 001064

TABLE III--2

COMPOSITION OF TALC MINED IN THE UNITED STATES

Location	Mineral Composition and Impurities	Commercial Use
Alabama	Principally talc with minor chlorite, traces of magnesite, quartz .	Rubber paint, textiles and cosmetics
Arkansas	Talc mixed with dolomite, magnesite and chlorite, minor quartz and calcite	Rubber insecticides, wall tile
California	Principally talc and tremolite with minor forsterite, serpentine, and carbonates impurities are chlorite, quartz, phlogopite, pyrite, and iron oxide	Rubber, pottery, paint, ceramics, paper, textiles, steatite, pharmaceuticals
Georgia	Talc with minor magnetite, carbonates impurities are pyrite, chlorite, quartz, feldspar, actinolite, and sericite	Crayons, paint, rubber, roofing, insecticides, lubricants, foundry facings, cosmetics
Montana	Essentially talc with minor impurities such as chlorite, graphite, dolomite	Cosmetics, steatite, paints, paper, ceramics
New York	Proportion of tremolite, anthophyllite, talc, and serpentine varies widely, any may predominate, but tremolite rock is most common impurities are quartz, carbonate, diopside, manganese, and iron oxides	Largely ceramics and paint, also rubber, plastics, insecticides, and foundry facings
North Carolina	Principally talc, traces of chlorite, dolomite, quartz and tremolite	Cosmetics, steatite, pharmaceuticals, rubber and paint
Texas	Essentially talc; impurities are various amounts of quartz, carbonate, and organic material	Chiefly wall tiles also insecticides
Vermont	Essentially talc with minor magnetite, chlorite, and sulfides	Paper, rubber, textiles, paint, roofing, crayons facings

WCD 001095

Historical Reports

In 1898, Thorel [10] published the first description of talc pneumoconiosis (talcosis) in a 44-year-old female worker who had been exposed to what the author called "soapstone" in a factory for a period the author described as "long". At autopsy, Thorel found talc dust in the walls of the alveoli and nodular lesions with macrophages, giant multinucleated cells, and granulation tissue. Carozzi [11] reported on a case of pneumoconiosis in a woman who had worked several years in an atmosphere of a talc dust. In this instance, talc particles were found during autopsy through microscopic examination of the alveoli of the lungs and also in the conjunctival tissue of the eye.

In 1931, Zanolli [12] in Italy reported the case of a 27-year-old female rubber tire worker who was exposed to large amounts of a talc dust daily. After 5 years of exposure, the woman's lung roentgenogram showed reticulation and nodular shadows consistent with pneumoconiosis. She complained of digestive disturbances, a decrease in her sense of smell, and redness of the conjunctiva and burning of the eyes. No data on the composition of the talc or exposure concentration were provided in any of these early studies.

Conflicting accounts of the biological hazards from talc exposure were reported in early animal experiments. In 1921 Haynes [13] published the results of an extensive study on a variety of dusts. He exposed 12 guinea pigs to a talc dust for 2 hours/day for 2 weeks. The author did not report the composition of the talc or data on exposure concentrations. He found no

WCD 001066

pulmonary damage but noted a brisk bronchial and lymphatic removal. Based on these brief exposures, Haynes classified talc as nonharmful, since it caused no permanent damage to the lungs. Policard [141], however, in 1939 reported the results of a study of rats exposed 3 hours/day for 12 days to talc dust at what the author considered to be high concentrations. The talc was identified as industrial grade, foliated talc with a particle size of less than 5 μm; the exposure concentrations were not measured. Policard observed upper respiratory tract irritation and marked dyspnea (labored breathing). At necropsy, he saw dilatation of the bronchi, acute emphysema, and exudative alveolitis. In microscopic examinations, elimination through the lymphatic system did not appear to be extensive, and the talc particles were observed to have been trapped by alveolar macrophages without damaging these cells. There were insufficient data presented in these papers to determine whether the differences in responses observed were due to species differences, talc composition, or exposure conditions.

In 1939, Antopol [15] called attention to the risk of granulomas being induced by talcum powder following surgery. In two instances, microscopic examination revealed crystals of talc in some giant cells at the site of previous surgical procedures. In 1947, Simmons [161] reported on five surgical cases in which talc crystals were discovered in nodular lesions with foreign body reaction, also at the sites of previous surgeries. He also produced similar lesions using talc in mice.

Schulz and Williams [171], in 1949, were apparently the first to recognize that differences in the chemical composition and physical properties of talc

WCD 001067

might account for the different responses observed. After analyzing 51
986 commercial talcs, the authors picked seven with different silicate-carbonate
988 ratios and different amounts of tremolite and serpentine. These seven talcs
990 were sterilized, and 200 mc of 5% saline solutions of each was injected
991 intraperitoneally (ip) into guinea pigs. Microscopic examination showed that
992 talc particles were held in a local area by phagocytic cells of the macrophage
993 and giant cell type. Schulz and Williams reported the fibrosis occurred and
995 was limited to the area in which the foreign material was stored and that the
997 development of fibrosis was minimal compared to that produced by crystalline
998 silica. The greatest degree of fibrosis was produced by talcs with high
999 levels of tremolite and serpentine and a low level of carbonate, an early
1000 indication that talc occurring with asbestos may pose a greater health hazard
1002 than talc without asbestos.

1005 Effects on humans

1008 Since adequate information concerning the talc composition is often not
1009 presented in the biological and medical literature, the relative magnitude of
1011 the effects due to minerals occurring with talc is difficult to assess. For
1012 purposes of comparison, the studies on the respiratory health effects of talc
1013 on humans and animals will be presented according to the effect of: (1)
1014 nonasbestiform talc with or without free silica, (2) asbestiform talc with or
1016 without free silica, and (3). talc of unknown composition. Information on
1017 exposure concentration has also often been lacking and those estimates, where
1018 given, will be converted to mg/cu m using a factor recommended by ACGIH of 6

WCD 001068

mppcf = 1 mg/cu m [18].

Fristedt et al [19], in 1968, described five cases of pneumoconiosis found in a rubber manufacturing plant in Sweden in 1966. The talc used at this plant was mostly granular and contained less than 1% quartz, asbestos were not present. The five men who developed pneumoconiosis were 40-62 years old (average 57 years) and had 11-40 years (average 30.2 years) of exposure to talc. Of the five, three worked in the department that manufactured inner tubes where the dust concentrations were 22-99 mppcf (9.7 mg/cu m) (average 58.5 mppcf) during 1967. The remaining two workers were employed in the water hose department where the dust concentrations in 1967 were 10-121 mppcf (average 37 mppcf, 6.2 mg/cu m). Most of the dust particles in both departments were less than 5 fuls in length, but the percentages of needle-shaped particles of 5-20 fuls in length and above 20 fuls were 0-1.2 and 0.02-0.05%, respectively, in the inner tube department and 0.7 and 0.03% in the water hose department.

Of those employed in the inner tube department, two had mild talcosis without impairment of lung function, while the third had stage III pneumoconiosis with a slight reduction of lung function (the type of lung function test was not mentioned). The worker who suffered from stage III pneumoconiosis also had rheumatoid arthritis; this diagnosis coincided with that of Caplan's syndrome (rheumatoid arthritis and pneumoconiosis). The author observes that the development of pneumoconiosis is often faster in workers with this syndrome and may occur after a relatively short exposure. Stage I talcosis without impairment of lung function was diagnosed in one

WCD 001069

subject working in the water hose department, while another worker in the same department, who also had 9 years of exposure to quartz sand from working in a iron foundry, had mild talcosis or talcosilicosis. A lymph node biopsy examination from the mediastinum of one of the workers revealed fibrosis and high (no values given) concentrations of talc with small amounts of birefringent crystals (alpha-quartz), accounting for about 5% by weight of the quantitity of the talc.

Scansetti et al [20], in 1982, reported the results of an examination of 72 workers exposed to a nonasbestiform, silica-free talc (mined at Val Chisone) during the processing of rubber. Chest x-ray films were taken, medical histories were investigated, and pulmonary function measurements were performed on the population of workers. The concentration of talc at which the workers were exposed was not discussed, and the average length of exposure was 7.1 years.

Although a low incidence of bronchitis (8%) and emphysema (5%) was reported, the roentgenographic pictures of 50% of the workers showed varying degrees of x-ray abnormalities [20]. Furthermore, the percentages of workers having abnormal x-ray film findings increased with the duration of exposure. Workers employed <3 years showed mostly normal results (80%), whereas 78% of those employed >6 years showed x-ray film abnormalities. Although the authors speculated that roentgenographic pictures might not show an increase in severity with the passage of time in individual workers, there was no follow-up of those involved in this study. The pulmonary function measurements were not discussed, and the criteria for diagnosis of bronchitis and emphysema were not

WCD 001070

mentioned.

Moskowitz [21] in 1970 reported the case of a 31-year-old woman who worked as a quality control inspector in a plant which manufactured a talcum powder aerosol. Part of her job consisted of spraying the contents of the can into the air briefly. She estimated that she sprayed 25-50 cans/hour in this manner and did this work, without respiratory protection, 1 week out of every 6 for a period of 6 years. No estimate of exposure concentration was given.

The woman was examined because of an increasing severe, persistant and productive cough of approximately 9 months' duration [21]. Her pulmonary vital capacity was reduced to approximately 38% of predicted and an open-chest lung biopsy found lesions similar to those described by Miller [22] including granulomas in a fibrotic stroma. The author reported a successful treatment of the patient due to cessation of talc exposure and treatment with the antiinflamatory agent, prednisone.

Man and Gracey [23] in 1972 also reported a case of pulmonary talcosis occurring in a 38-year-old male truckdriver who, for 20 years, had dusted himself at least twice daily and for 4 years at least three times a day with a cosmetic talcum powder. Following hospitalization due to postprandial vomiting, chest X-ray films of the man revealed a diffuse nodular infiltrate in both lungs, and a gross examination of the lungs revealed multiple pale yellow nodules scattered throughout all the lobes. In addition, a microscopic examination revealed diffuse interstitial inflamatory cell accumulation with birefringent crystal in alveolar spaces and interstitial tissues. The authors concluded that it was likely the patient had developed pulmonary fibrosis from

WCD 001071

his use of talcum powder.

Talcum powder has produced cyanosis, labored breathing, intense to moderate agitation, coughing, and tachycardia in infants who accidentally ingested or inhaled large amounts [24]. Investigators have reported bronchial obstruction, bronchiolar inflammation, rales, emphysema, atelectasis, edema, and death in similar cases [25,26,27,28,29,24,30, 31].

Various deposits of talc contain asbestiform contaminants such as tremolite, anthophyllite, or chrysotile. A number of reports have described the structure of the lungs and the pulmonary functions of workers exposed to talcs containing asbestiform contaminants. Although these studies yield information concerning the pneumoconiotic disease process and help to relate exposure to health effects of workers, it is particularly difficult to separate the effects of asbestos and silica from those of talc alone in these studies.

Dreessen [32] reported in 1933 on 57 workers in a mine producing talc which contained tremolite. Dust samples were taken with an impinger, and the average concentration at the drill face was 1,440 mppcf (240 mg/cu m). Millers were exposed to an average of 52 mppcf (8.7 mg/cu m), whereas the air outside the mill contained 4 mppcf (0.7 mg/cu m). The author noted that 88% of the talc sampled was < 5 u in diameter, and that none of the particles exceeded 6 u in diameter. Although a complete analysis of the talc was not presented, Dreessen reported finding no free silica in the form of quartz and stated that talc and tremolite occurred in about equal proportions (45%).

In 67% of the talc workers, he found, radiologically, that fibrosis was

WCD 001072

were extensive than usual, and he also found 28% with stage I pneumoconiosis,
2% with stage II pneumoconiosis, and 5% with normal lungs (32). Stage I
pneumoconiosis was described by Dreesson as a "diffuse, fine, generalized
fibrosis...chiefly confined to the lower two-thirds of the lung fields," and
it appeared to cause little disability.

The occurrence of the fibrosis and pneumoconiosis observed appeared to be associated increasing levels of exposure. All the group with levels of exposure averaging 1,440 mppcf (240 mg/cu m) had a diagnosis of fibrosis (40%) or pneumoconiosis (60%), the group with levels averaging 32 mppcf (6.6 mg/cu m) had a 9% occurrence of fibrosis of pneumoconiosis, with the percentage of workers diagnosed as pneumoconiotic decreasing from 60 to 30%, and the group with levels averaging 4 mppcf had an 8% incidence of fibrosis with no pneumoconiosis observed. Although the measured concentrations of talc dust may not be accurate in this early study, the trend of increasing severity of effects with exposure is apparent.

In 1935, Dreesson and Callaballa (33) studied two Georgia talc mills and mines and reported on 68 workers exposed to tremolitic talc. Talc dust samples were taken with an impinger, and the average exposure concentration for the miners was 32 mppcf (5.3 mg/cu m). In the mills, analysis of the dust samples showed an average of 70% talc, 20% dolomite, and 10% tremolite. Only occasional fragments of free silica in the form of quartz were found and these were too few to be considered significant by the authors. The median size of the particles found was 8 (um, and 45% of these were >5 (um.

Roentgenographic examinations showed that 16 of 23 millworkers and 6 of 13

WCD 001073

miners exposed to tremolitic talc dust at these concentrations had talc
1180 pneumoconiosis.

1182 The talc to which workers were exposed in this study [33] contained about
1183 a fourth as much tremolite as that reported in an earlier study [32] by the
1184 same author. Dreesson and DalleValle concluded that high levels of exposure
1185 to talc with low levels of tremolite was more hazardous to workers' health in
1186 this case than lower levels of exposure to talc with the higher concentrations
1187 of tremolite, based on the greater frequency of severe pneumoconiosis seen in
1188 the second group studied.

1190 A comparison of the two studies supports Dreesson's conclusion that the
1191 concentration of talc that the worker is exposed to may be more important in
1192 the causation of pneumoconiosis than the mineral composition of the dust.
1194 In a roentgenographic examination of 221 male talc miners and millers in 1943
1195 exposed to a tremolitic talc containing 1% or less free silica at dust levels
1197 of 0-5,000 mppcf (1-633.3 mg/cu m) in mining operations and of 20-215 mppcf
1198 (3.3-35.8 mg/cu m) in milling operations, Siegal et al [34] found 32 (14.5%)
1199 with marked fibrosis based on the interpretation of X-ray films. Other
1200 workers were found to have mild or moderate fibrosis but no further
1201 information was supplied by the author concerning these workers. In terms of
1202 duration of employment, 6/8 (74%) employed for 30 years or more, 36/91 (29%)
1203 employed for 10-30 years, and 0/16 (0%) employed for 410 years showed evidence
1205 of marked fibrosis. Eighteen of the 32 men had been exposed to talc only.
1207 The fibrosis was reportedly disabling with fine and diffuse characteristics
1208 and a roentgenographic appearance of granulation or nodulation on a hazy

WCD 001074

background. Talc plaques on the pleural surfaces were found in 14 of the 226 workers (6.2%).

A followup examination on this same population 10 months later, focusing on selected men who had fibrosis and who were previously exposed to tremolitic talc dust, showed that 17 of 18 with advanced fibrosis were 40 years of age or older and were exposed to talc for 10 or more years (the age of the other man and his duration of exposure was not reported [34]. Of the 18 men with fibrosis, 13 had 1 or more respiratory symptoms, 10 complained of labored breathing, 7 of chronic cough, 5 of excessive fatigue and 3 of chest pain. The author noted the presence of pleural calcifications and the similarity of this pneumoconiosis with that produced by asbestos

In a study 14 years later, Kleinfeld et al [35] described the condition of the 32 men with marked fibrosis from the study of Siegel et al [34]. By this time, control measures had been instituted and dust concentrations had been reduced in the work environment to 3-6 mppcf (0.5-1.3 mg/cu m) in the mining operations and 3-63 mppcf (0.5-10.5 mg/cu m) in the milling operations [35]. Nineteen of the 32 had died, 4 from pneumoconiosis and 15 from causes said have been unrelated to talc exposure. Of the 13 alive (6 still employed), the outstanding clinical features involved the pulmonary and cardiovascular systems manifested as labored breathing, coughing, emphysema, basal rales, diminished chest expansion, and clubbing of fingers. Roentgenographic examinations showed a diffuse infiltration of the basal and midzone fields, occasional nodules, and cor pulmonale. In addition, talc plaques were observed in the region of the diaphragm and pericardium and in parts of the

WCD 001075

lung fields. Abnormal electrocardiograms were observed in six. Kleinfeld noted that the observed clinical features of this group suggested serious disorders of the pulmonary and cardiovascular systems. He noted that progression of disease appeared to be present in all workers although the course of disease was usually slow. Kleinfeld did not attempt to separate the normal effects of aging from the progression of the disease nor did he investigate the smoking habits of the workers.

A number of other studies examining the respiratory systems of talc milling workers have been reported by Kleinfeld et al [36,37,38,39,40]. Kleinfeld et al [37] in 1963 studied six cases of pneumoconiosis. The men (age 42-67 years) had been exposed to a talc dust containing unspecified amounts of tremolite, anthophyllite, and approximately 5% free silica for an average of 24 years. Estimated talc dust exposure concentrations were 29-470 mppcf (average 157 mppcf), [26.1 mg/cu m]. The major clinical features observed were chronic productive cough, labored breathing, diminished breathing sounds, limited chest expansion, diffuse rales, and clubbing of fingers. Cor pulmonale was present in four patients. The most frequently observed abnormal changes in the lungs were a diffuse fibrosis, the presence of macrophages with absorbed dust particles and asbestos bodies, granulomas, alveolar cell metaplasia, bronchiectasis, emphysema, silica-like nodules, and pleuritis. A pattern of endarteritis consisting of intimal hypertrophy and reduplication was common, and four cases had hypertrophy of the right ventricle. The authors stated that these changes were consistent with those seen in pulmonary hypertension.

WCD 001076

In a case control study performed in 1965 [36], pulmonary functions were investigated in 43 milling operation workers exposed for more than 10 years (average 19 years) to a talc dust containing tremolite, anthophyllite, serpentine, and 5% free silica at a weighted mean concentration of 62.3 mppcf (10.4 mg/cu m). These workers were 26-59 years old (mean 50.1 years), forty-one workers of similar age range, 32-71 years (mean 48.8 years), and smoking habits but with no exposure to talc were used as controls.

The predominant clinical symptoms and signs observed in these talc workers were labored breathing (65.1%), cough (32.6%), lung crepitations (21.9%), and clubbing of fingers (18.6%). None of the controls had coughing or clubbing of fingers, and only 4.9% and 7.3% developed labored breathing and lung crepitations, respectively. The differences in the incidences of these symptoms in talc workers and controls were statistically significant ($0.01<P<0.05$). In either group, no individual had abnormal electrocardiographic findings consistent with cor pulmonale.

Five pulmonary function tests were performed, including vital capacity, 1-second vital capacity, residual volume, total lung capacity, and pulmonary diffusion capacity for carbon monoxide [36]. Except for residual volume, the talc workers had lower mean values than the controls for each function. Mean values for vital capacity and total lung volume for the controls were generally about 100% of predicted values, whereas the talc workers measured at 79.7 and 84% of predicted values, respectively ($P<0.01$, $P<0.05$). The 1-second vital capacity was reported in terms of the percent of vital capacity, and the means were 71.8% for talc workers and 76.2% for controls. For the pulmonary

WCD 001077

diffusion capacity, the talc workers had a mean of 24.2 cc/mmHg/minute, and
the controls had 27.3 cc/mmHg/minute

Roentgenographic examinations revealed that 16 of the 43 talc workers had positive pulmonary infiltration, whereas none of the controls had such changes [36]. The authors further investigated the difference in clinical findings and pulmonary function changes between those exposed workers with and without pulmonary infiltration. The incidences of coughing, labored breathing, lung crepitation, and clubbing were found to be significantly higher ($0.01<P<0.05$) in workers with pulmonary infiltration. However, only vital capacity and diffusion rate were significantly low ($0.01<P<0.05$) in those having pulmonary infiltration. The author stated that a strong correlation was not found between pulmonary function measurements and the clinical, roentgenographic, and environmental findings.

The pulmonary ventilation function of 20 talc workers who had developed talcosis of the lungs (presence of positive clinical and roentgenographic findings) was also investigated by Kleinfeld et al [38]. In this study, all workers had been exposed to talc dust admixed with minerals such as tremolite, anthophyllite, and free silica for (1-40) years (average 23 years) at a concentration exceeding 50 appcf (8.3 mg/cu m). The pulmonary function of these workers was affected as in previous study [36], and the tests indicated the presence of restrictive or obstructive breathing disorders, according to the authors.

In another similar study [39] in 1965, 16 talc workers with different degrees of pulmonary fibrosis (indicated by roentgenographic findings) were

WCD 001078

examined. These workers, 19-69 years old (mean 54.8 years), were exposed
primarily to a talc mixed with tremolite, anthophyllite, serpentine, and less
than 5% free silica for 13-26 years at a TWA concentration of 68.9 mppcf (11.5
mg/cu m). A number of these workers developed labored breathing and impaired
ventilatory function and diffusion capacity.

The studies of Weinfeld et al [36,38,39] indicate the presence of
radiological findings of fibrosis, various decreased pulmonary function
measurements and an increased occurrence of clinical signs and symptoms of
respiratory disease in workers exposed to tremolitic talc with a silica
content of 5% or less. However, these studies lack information concerning
smoking history and comparisons with control group of a similar composition as
the workers. The lack of strong correlation of pulmonary function
measurements of individuals with abnormal clinical and radiological findings
might be explained by the heterogenicity of the sample population of workers
and the severity of the pneumoconiosis.

Miller et al [22] in 1971 reported the case of a 62-year-old male who
cleaned ventilators that collected excess talc dust (predominantly pure talc
with some traces of anthophyllite) for 9 years in a factory that produced
rubber condoms.

Eleven years after leaving that job, he was admitted to a hospital
complaining of increasingly labored breathing, wheezing, coughing and
expectoration [22]. Following hospitalization, progressive cor pulmonale
developed and the patient died approximately 1 year later of cardiopulmonary
insufficiency. An open-chest lung biopsy examination performed after

WCD 001079

hospitalization found fibrosis of the lung parenchyma and granulomas formed by
epithelioid and multinucleated giant cells surrounded by a thin layer of
lymphocytes. The lung was found to be emphysematous with thin alveolar septa
and the pleura was thickened and fibrotic, with granulomas similar to those
found in the pulmonary parenchyma. Talc particles could not be found by light
microscopy but were found in large amounts after ashing of the lung samples by
the use of X-ray diffraction, electron microscopy and a polarizing microscope.

Studies have also been located that indicated adverse health effects on
workers who had exposure to talc whose precise mineral composition was not
known with certainty. Although the author's descriptions in these studies do
not preclude exposure to traces of asbestos with these talcs, the authors
indicate that exposure was to talc not containing free silica.

In 1955, Alivisatos et al [41] described an unusually rapid development of
talcosis in eight workers engaged in pulverizing pieces of a talc rock by hand
in electrically operated mills, or in packaging the powder in sacks. The
talcs used in these plants contained 48-52.2% silicate salts (estimated as
silicic acid) but no free silicic acid (silica). While the number of particles
of some samples in the vicinity of the mills and transportation areas were
described as being "immeasurable" (not measurable with available sampling
equipment) the concentrations of most samples from various plant areas ranged
between 11.6 and 60.8 mppcf (1.9 and 10.1 mc/cu m), and the diameters of 43-
98% (average 70.5%) of the particles were 5 (um or less.

Of the eight workers, aged 22-49 years (average 35 years), who developed
talcosis, six had worked for 18-26 months and one for 40 and another for 60

WCD 001080

months in this factory [41]. The first clinical signs and symptoms of
1413 talcosis such as a productive cough, mucopurulent sputum, and labored
1414 breathing on exertion were found as early as 16 months on the job. One worker
1415 presented casts of talc in the sputum. Some of these workers also suffered
1417 from general weakness and had lost weight as the disease progressed. Ten
1418 months after these examinations, one of the eight workers who developed
1419 talcosis died of pulmonary failure.

1421 Chest x-ray films of three of these seven workers revealed stage III
1422 pneumoconiosis characterized by mottling and nodular shadows of "tumor-like"
1423 appearance in both lungs, and confluent shadows in some areas [41]. Two
1424 workers exhibited stage II pneumoconiosis consisting of scattered and
1425 confluent mottling in both lungs, and two exhibited stage I pneumoconiosis
1426 composed of reticulation and scattered mottling in both lungs.

1429 For 7 of the eight workers, blood gas analysis and pulmonary function
1430 measurements were reported. The values of vital capacity and maximum
1431 breathing capacity, percent arterial blood oxygenation, and arterial partial
1432 pressures of oxygen were lower in the workers than predicted values. The
1434 average ventilations/minute/sq m, arterial and alveolar partial pressures of
1435 carbon dioxide, and transfer gradient for oxygen across the lung tissue were
1436 higher than predicted. This respiratory syndrome indicates that the transfer
1437 of O2 through the lung tissue is being obstructed and that an adaptive
1438 mechanism of increasing ventilation exists.

1441 Of the four workers whose CXR's were examined, the results of three were
1443 described to be within normal limits, while those of the fourth indicated a

WCD 001081

slight degree of anemia [41]. Erythrocyte sedimentation rates (ESRs)/hour were between 14 and 38 mm (average 27 mm) for the eight workers with six of the eight values of the ESRs higher than the normal value of 15 mm/hr. The increase in ESRs are an indication of tissue damage that is not specific for pulmonary lesions. All sputum tests for mycobacterium tuberculosis were negative.

Allivisatos et al [41] concluded that exposure to talc can result in a pneumoconiosis with lung function disturbances, which they labeled as a definite progressive disease and that could lead to pulmonary failure and death. The authors opined that the "tumor-like" appearances on X-ray films of the three workers with stage III pneumoconiosis were due to talc obstructions in the bronchioles which caused areas of atelectasis. They also suggested that the unequal distribution of oxygen throughout the lung parenchyma was the probable cause of the higher transfer gradient in workers who had pneumoconiosis. They attributed the rapid development and progression of pneumoconiosis in their patients to the high atmospheric concentrations of talc particles with a diameter of 5 (um or less despite the absence of free silica in the talc.

In 1979, El-Ghawabi et al [42] reported the incidence of pneumoconiosis among Egyptian workers engaged in the milling of a talc. Chemical analysis of the talcs handled in the plant showed 55.8-61% silicate, 0.35-5.95% ferric oxide, 1.01-3.05 aluminum oxide, 0.13-1.71% calcium oxide, 0-0.32% chromic oxide, 28-33.13% magnesium oxide, and 0.02-0.18% moisture. The talc did not contain free silica. Analysis of air samples taken at the breathing zone of

WCD 001082

the workers in various work areas revealed mean dust concentrations of 25-11
1482 appcf (4-18.5 mg/cu m) and a mean particle size of <5 fuim in 95-99% of the
1483 samples. Of the 50 men employed at the plant, 6, 18, 17, and 9 were,
1485 respectively, 20-29, 30-39, 40-49, and above 50 years of age and had had
1486 varying lengths of exposure to talc. Sixteen workers (32%) had been exposed
1487 for 15 years or more.

1489 El-Ghawabi et al [42] found 16 cases of pneumoconiosis (32%) among these
1490 50 workers. Nodular and conglomerate shadows were observed in the chest X-ray
1492 film studies of 10 workers (average age 50.4 years) who had 17-35 years
1493 (average 26.2 years) of exposure, while the remaining 6 (average age 41.8
1495 years) who had 4-35 years (average 17.5 years) of exposure had linear and
1496 reticular opacities. In addition to the 16 persons with pneumoconiosis, three
1497 had increased lung markings suspected to indicate early pneumoconiosis. Two
1500 men had shadows in their X-ray films suggestive of tuberculosis, one of them
1501 having extensive pulmonary and pleural fibrosis and marked impairment of lung
1503 function. Values of the lung function tests for the rest of the workers were
1504 within normal limits. No abnormalities were found in the chest X-ray films of
1505 the workers younger than 30 years of age which suggests that a combination of
1507 age and duration of exposure are factors which will affect the manifestation
1508 of the disease.

1510 The formation of granulomas due to talc exposure have historically been of
1511 great concern in the medical profession because talc has been widely used as a
1512 dusting powder in gloves and rubber articles used in surgical procedures.
1513 Talc is thought to gain entry into the body during surgical procedures and act

WCD 001083

as a foreign body irritant, resulting in the formation of granulomatous
1515 lesions [42,44,45]. The only types of nonrespiratory granulomas that are
1517 likely to be of any occupational concern, however, is a skin granuloma of the
1518 type reported by Tye et al [45]. Tye et al reported that a 45-year-old woman
1520 developed hundreds of talc granulomas on the skin from the daily application
1521 of talcum powder to draining and incised boils on the shoulders, buttocks and
1522 thighs. Transmission electron microscope and X-ray diffraction confirmed the
1523 presence of talc within the granulomas [45]. This case suggests the
1525 possibility of granuloma formation in workers with open skin wounds. The eye
1526 lesion reported by Wanda et al was found in 5 month old girl. The child was
1527 examined for hyperemia and hemorrhaging of the conjunctiva of the left eye.
1528 Crystals resembling talc and similar to those found in the baby powder used on
1530 the infant were found in the lesion. The authors believed that the lesion was
1531 caused by air-borne particles of baby powder and produced a similar lesion in
1532 the fornix conjunctiva of a rabbit with the baby powder [46].

1535 Another potential route of exposure for talc particles is via ingestion in
1536 the diet or from respirable and nonrespirable particles trapped in the mucous
1537 secretions of the upper respiratory tract. The effects of talc in the human
1538 diet are not known but have recently been the subject of speculation.

1541 A 24-nation study of age adjusted mortality for stomach cancer in 1962-
1542 1963 showed that Japanese men had the highest incidence of all nations [47],
1543 as much as 7 times that of men in the United States [48]. Native and
1544 immigrant Japanese consume larger quantities of talc-coated rice, and the
1545 incidence of gastric cancer appeared to be associated with this fact. Based

WCD 001084

on these observations, Merliss [47] hypothesized that the consumption of rice coated with a talc containing asbestos was a causative factor of stomach cancer.

Matsuda et al [49] stated that talc appeared to be present on the surfaces of unwashed talc-coated rice, on the surfaces of washed and cooked rice, in the wash water from the rice, and within the cells of gastric carcinomas from six Japanese patients. The authors studied the structure and calculated the magnesium-to-silicon ratios and confirmed that the particles from these samples were of similar composition and that the talc found in cancer cell specimens came from talc ingested with rice. This finding seems to supports the hypothesis of Merliss [47], but it has been criticized by Pooley and Stewart [50] on the grounds that the magnesium-to-silicon ratios used by Matsuda et al [49] to identify talc were not correct, and that the morphologic features of the spherical particles called talc by Matsuda et al were actually characteristic of starch rather than talc. Further research is still required concerning the etiology of gastric cancer among the Japanese.

Talc particles have been found embedded within human tissues of primary ovarian, endometrical, and cervical carcinomas by Henderson et al [51], using the extraction-replication technique (a method for preparing tissue for electron microscopy). The authors did not comment on how the talc may have reached the ovaries and other reproductive tissues. However, they suggested that indistinguishable characteristics of talc from anthophyllite asbestos by use of this technique made it impossible to incriminate talc as the primary cause of the carcinomatous change in any of the tissues.

WCD 001085

Epidemiologic Studies

A number of epidemiologic studies of occupational exposure to asbestiform and nonasbestiform talc containing various amounts of free silica have been reported in the literature.

In 1977, Saleven et al [52] reported on mortality in miners and millers of Vermont exposed to talc that did not contain asbestiform minerals such as tremolite, anthophyllite, chrysotile. Historical monitoring data were not adequate to estimate cumulative exposures to talc, but the authors indicated that it was not uncommon for concentrations of the respirable talc dust to exceed 20 mppcf. Records of surveys by the Vermont Health Department were used in an epidemiologic study. Since 1937, workers in dusty trades in Vermont have had chest X-ray films taken annually by the state health department. Workers who had been employed in the Vermont talc industry for at least 1 year between 1940 and 1969 and who had had at least one chest X-ray film taken during the survey were included in the study, and their status from 1940-1975 was ascertained. Deaths were analyzed for the whole study group of 392 workers, and for the 225 employed as millers and 163 employed as miners for at least 1 year. Since the groups were not mutually exclusive, 47 workers were included in both categories. Expected numbers of deaths from various causes were estimated using age- and time-specific death rates for the white male population of Vermont and of the United States. Determination of the statistical significance of the differences between numbers of observed and expected (O/E) deaths was based on the Poisson distribution.

WCD 001086

At the end of the study period, 294 of the 392 talc workers (76%) in the study were alive, 90 (23%) had died, and the vital states of only 4 (1%) was not known [52]. Based on United States rates, the number of deaths from all causes in Vermont talc workers was elevated (90 observed, 77.32 expected), although it was not statistically significant. Nearly all the excess was accounted for by an increase in deaths from other nonmalignant respiratory diseases (ONMRD), excluding pneumonia and influenza.

For the 11 talc workers who died of ONMRD, the average duration of exposure to talc was 18 years (SD=11) with none exposed less than 5 years, the average interval between first employment and death was 31 years (SD=12), and the average age at death was 60.5 years (SD=9) [52]. At least 8 of the 11 smoked, 1 did not smoke, and information was unavailable for 2 workers. Only 1 of those who died of ONMRD had worked in a talc mine but not in a mill. He had worked in the mine for 16 months, had been exposed to asbestos for 18 months, smoked, and had died at the age of 43. A second worker had been exposed to dust in a feldspar quarry, but the other eight had not been previously exposed to dust in the workplace.

Differences in deaths from other causes were not statistically significant, although deaths from respiratory cancer were slightly elevated (6 observed, 3.67 expected). Based on United States mortality rates, the O/E ratios of deaths from ONMRD were 4.34 in talc millers (7 observed, 1.72 expected, P<0.01), 1.05 in talc miners (2 observed, 1.91 expected), and 0.11 in all talc workers (11 observed, 1.79 expected, P<0.01). Although ONMRD mortality rates were greater for Vermont men than for men in the United

WCD 001087

States, mortality from ONMRD was still significantly greater in Vermont talc
millers than in Vermont men. Based on state mortality rates, the O/E ratios
of deaths from ONMRD were 5.30 in men employed as talc millers for at least 1
year (7 observed, 1.33 expected, P<0.01), and 6.73 in those employed as
millers for at least 5 years (7 observed, 1.04 expected, P<0.01).

Readable chest X-ray films were available for 8 of the 11 who died of ONMRD (52). Findings indicative of pneumoconiosis were classified as 2/3 for 2 workers, 2/2 for 3 workers, 2/1 for 1 worker, and negative for 2 workers. All chest X-ray films classified as 2/1 or greater had small round opacities evenly distributed throughout the lungs, which, according to the authors, were of the type usually observed in workers having pneumoconiosis. Including qualitative roentgenographic readings by the Vermont Health Department, 9 of the 11 who died of ONMRD (82%) had X-ray film findings indicative of pneumoconiosis while they were actively employed.

By reviewing work histories, Selevan et al (52) reported that five of the six deaths from respiratory cancer occurred in men who had worked in the mines (the work location of the sixth man was not known). In the 163 men employed as talc miners for at least 1 year, 5 deaths from respiratory cancer were observed, compared with 1.22 expected, based on Vermont rates (P<0.05) and 1.09 expected based on United States rates (P<0.01). However, in the 82 employed as talc miners for 5 or more years, 3 deaths from respiratory cancer were observed, compared with 0.41 expected based on Vermont rates and 0.71 expected based on United States rates. Thus, differences between numbers of observed and expected deaths from respiratory cancer were statistically

WCD 001088

significant for men employed as talc miners for at least 1 year. None of the 6 had been previously exposed to dust in the workplace, and at least 3 of them had smoked. The average age at death was 58.2 years (SD=14.5), and the average interval between first employment and death was 27.5 years (SD=15.8). The number of years of employment varied considerably: two had worked for 2 years, one for 5 years, one for 8.5 years, one for 18.4 years, and one for 40.7 years.

The study by Selevan et al [52] has shown that workers exposed to nonasbestiform talc were subject to an increased risk of death from DNMRD, and that most of those who died from this cause had had roentgenographic evidence of pneumoconiosis while they had been actively employed.

The findings for respiratory cancer are difficult to interpret. Concentrations of airborne talc were probably greater in mills than in mines, however most of those who died of respiratory cancer were miners. Their durations of exposure to talc varied considerably, from 2.0 to 40.7 years. This variation tentatively suggests that the excess of deaths from respiratory cancer may be more closely related to exposure to a cofactor or to a confounding factor rather than to talc alone.

It is unfortunate that adequate employment records were not available from Vermont talc operations. Otherwise, the authors could have obtained more precise estimates of the population of workers exposed to talc than those derived from the roentgenographic surveys, and the observed mortality in these workers would have been more comparable with estimates of expected mortality based on rates for either Vermont or the United States. Selevan et al [52]

WCD 001089

did not conclude whether or not nonasbestiform talc miners had an increased risk of death from respiratory cancer, although they indicated that the possible role of exposure to radon daughter emissions in talc mines cannot be eliminated. Radon daughter levels in Vermont talc mines, measured by MESA, ranged from trace quantities to 0.12 working levels; a single reading as high as 1.0 level had also been recorded.

A study of mortality in miners and millers exposed to nonasbestiform talc from the Germanasca and Chisone Valleys in Italy was reported by Rubino et al (53) in 1976. Using company and town records, the investigators (53) individually matched 1,346 of the miners (89%) and 438 of the millers (92%) whose vital status in 1949 to mid-1974 was known with controls of the same age from a nearby agricultural town. Because of criticism that pneumoconiosis was also found in the control population, Rubino et al reanalyzed this same data in a subsequent publication (54), using Italian national statistics for comparison. The comparisons did not find a statistically significant increase in the incidence of cancer, including that of the lung or stomach. However, the O:E ratio of deaths in miners from nonmalignant respiratory diseases increased as cumulative exposures to respirable talc increased, and also as the latent periods between first exposure and death increased. In millers, however, the distribution of deaths from nonmalignant respiratory disease could not be shown to be related either to cumulative exposures to talc alone or to the latent period.

Because the risk of death from nonmalignant respiratory disease was significantly elevated in miners but not in millers, the authors concluded

WCD 001090

that these deaths were attributed to exposure to the airborne free silica present in talc mines rather than to talc alone. Until 1960, however, concentrations of respirable dust were greater in the mines than in the mills. Although dust in the mines contained 1-18% free silica, miners in this study were still exposed to more respirable talc dust than were millers. Thus, another explanation of the authors' finding is that cumulative exposure to talc in the range to which millers were exposed significantly increased the risk of developing nonmalignant respiratory disease.

In 1976, Fine et al [55] reported a study of respiratory morbidity in 91 rubber workers exposed to a nonasbestiform talc at concentrations below the current TLV of 20 mppcf (3.3 mg/cu m) during the manufacture of uncured rubber products. The airborne talc dust yielded less than 2 fibers/cc >5 (u)m in length (in 12 samples) and <1% free silica (in 18 of 21 samples). Sixty workers (11 were absent) were exposed to respirable talc at less than 1 mg/cu m (range 0.58-3.55 mg/cu m) for an average of 8.9 years (SD=6.5). Fine et al estimated that average cumulative lifetime exposures to nonasbestiform talc were about 20 mppcf, and maximum exposures were about 60 mppcf (10 mg/cu m) in these rubber plants.

The 80 workers exposed to talc were matched by age and length of employment with 189 men from other areas of the plants who were not exposed to talc, curing fumes, or carbon black [56]. Twenty-five of the 80 workers worked in a plant where they were exposed only to talc, and 55 worked in another plant where they were exposed to talc and curing fumes. Information on previous occupations, medical history, smoking habits, and respiratory

WCD 001091

symptoms was obtained during workshifts by trained interviewers using a modified version of a questionaire developed by the British Medical Research Council (BMRC). Indices of pulmonary function, including FEV 1 and flowrates at 12.5, 25, and 50% of FVC, were measured during workshifts using a spirometer. FEV 1 and FVC were also measured for 28 workers exposed to talc before and after the first workshift following a 2-day weekend. Posteroanterior and lateral roentgenograms were taken for all but four workers. These were reviewed and classified by the UICC-Cincinnati classification system for pneumoconiosis by a physician certified as a reader by NIOSH.

Factors that could have influenced respiratory symptoms, such as age, height, length of employment, and smoking habits, were found to have been similar in the workers exposed to talc and control groups (55). The percentage of workers who were former or current cigarette or cigar smokers were similar in the two groups. The exposed group had smoked an average of 12.8 years (SD=12.6) and the control group an average of 12.7 years (SD=12.8).

Percentages of respiratory symptoms in smokers and nonsmokers in the group exposed to talc and in the control group are summarized in Table III-3 (55).

WCD 001092

TABLE III-3

PERCENTAGES OF RESPIRATORY SYMPTOMS IN WORKERS EXPOSED TO NONASBESTIFORM TALC AND IN CONTROLS*

Symptoms	Nonsmokers (number of men)			Smokers** (number of men)		
	Talc (122)	Control (61)	Difference	Talc (56)	Control (138)	Difference
Chronic bronchitis symptoms (means hypersecretion)						
Cough for 3 mo	4.5%	-	+4.5%	25.9%	10.1%	+15.8%
Phlegm for >3 mo	18.2	5.9	+12.3%	36.2	15.2	+21.0%
Obstructive respiratory disease symptoms						
Wheezing most days and nights	-	2.0	-2.0	22.4	6.5	+15.9
COLD***	-	5.9	-5.9	24.1	11.6	+12.5

*Talc workers and controls employed in rubber plant. Workers exposed to industrial grade nonasbestiform talc containing 1% free silica for av 8.0 yr. Most workers exposed to respirable talc at 4 mc/cu m at end of study.

**Former or current smokers of cigarettes, cigars, or pipes

***Chronic obstructive lung disease, wheezing most days and nights, grade 3 labored breathing, or FEV 1/FVC 100 60%

Adapted from Fine et al [55]

WCD 001093

For both smokers and nonsmokers, more workers exposed to talc had symptoms of chronic bronchitis indicative of mucus hypersecretion than did controls, although the increases were statistically significant ($P<0.006$) for smokers only [55]. The percentage of workers with wheezing during most days and nights was significantly elevated ($P<0.005$) in workers exposed to talc who smoked, but not in those who had never smoked. The increase in the percentage of men with one or more positive criteria for chronic obstructive lung disease (COLD) was greater in talc workers who smoked than in their controls, largely because of the increase in the percentage of men with wheezing. However, none of the exposed workers, including smokers, had labored breathing. The percentage of workers with colds during winter was slightly greater in exposed workers than in controls, although percentages of workers with bronchitis, pneumonia, or asthma were similar in both groups. Since increases in respiratory symptoms were found in workers exposed to both talc and curing fumes and to talc alone, Fine et al concluded that workplace exposure to talc was associated with increases in these symptoms. The magnitude of these increases may have been affected by exposure to curing fumes, however, as Fine and Peters [56] showed that exposure to curing fumes is also associated with an increase in symptoms of chronic bronchitis.

Comparisons of pulmonary function in talc workers and controls were limited to those in white men over 24 years of age [55]. Regression coefficients for age, height, and years of cigarette smoking were statistically significant ($P<0.004$, $P<0.000$) and ($P<0.005$) respectively for both talc workers and controls. The regression coefficient for years of

WCD 001094

exposure to talc was statistically significant (P<0.015) for workers exposed to talc, but not for duration of employment for controls. The regression analysis for 55 men exposed to talc alone indicated that, for each year of exposure to respirable talc dust, the workers' FEV 1 decreased an average of 33 cc more than decreases related to age and smoking habits. In 69 workers exposed to talc and curing fumes, regression analysis indicated that FEV 1 decreased by an average of 26 cc for each year of exposure. For 27 workers exposed for 10 or more years to talc and, in some instances, to curing fumes, measurements of FEV 1 were an average of 211 cc lower than predicted values derived from the control group after adjustment for differences in age, height, and smoking habits.

These findings indicated that FEV 1 decreased progressively as years of workplace exposure to talc increased (53). Since measurements of FVC were not affected by duration of exposure, the effects of talc on the lungs appeared to be primarily obstructive. None of the workers exposed to talc had chest X-ray film findings indicative of classical pneumoconiosis, but workers in this study were probably exposed to talc at much lower concentrations than were workers exposed to talc in other studies who developed labored breathing, pneumoconiosis, or fibrosis after many years of workplace exposure to talc.

Since workplace exposure to respirable talc dust at concentrations in the range of 0.5-1.0 mg/cu m could have led to progressive decreases in lung function measurements, Fine et al (55) suggested that cumulative exposure to respirable nonasbestiform talc dust should be restricted to 10-20 mg during working lifetime of 40 years. They suggested that a TLV of 0.25 mg/cu m

should limit impairment of lung function and should decrease the excessive prevalence of respiratory symptoms in workers exposed to talc.

In 1975 and 1976 Wagman et al [57] investigated the signs and symptoms of respiratory disease in workers currently employed at three major Vermont talc companies that process nonasbestiform talc containing small quantities of free silica. A modified ATS questionnaire was used to obtain information from each worker on past medical history, lifetime smoking history, and the extent of symptoms indicative of chronic bronchitis. Chest X-ray films were evaluated by at least two readers using the ILO/UICC classification system. Any discrepancies in the first two readings were resolved by a third reader.

Pulmonary function was measured with a spirometer, with FVC and FEV 1 derived from the mean of three successful trials using standard methods [57]. Maximum midexpiratory flow (MMEF) was taken from the reading with the largest sum of FEV 1 and FVC, and residual volume (RV) was derived by subtracting FVC from the total lung capacity (TLC). FEV 1, FVC, and MMEF were standardized using the predictive equations and the findings were expressed as the ratio of observed to expected values multiplied by 100.

Of the 174 employed at the 3 Vermont talc plants in 1975, 142 (82%) were included in the first survey; the other 32 were either not available or had refused to participate. The 1976 survey included 127 of the 142 (88%) in the first survey. Thus, findings from 117 workers in the 1975 survey were studied in the cross-sectional analysis, and findings from 102 workers in both the 1975 and 1976 surveys were compared in the longitudinal analysis designed to assess whether there had been a change in the signs or symptoms of chronic

WCD 001096

respiratory impairment within 1 year. For the 117 in the 1975 study, the average age was 40.6 years (SD=11.0), they had smoked an average of 21.9 years (SD=11.2), and they had been employed in talc operations for an average of 8.5 years (SD=8.5).

Although not discussed in detail, the authors [57] indicated that, in the 1975 study, workers exposed to talc who had a variety of symptoms appeared to have more impairment of lung function than did those without symptoms. Abnormal lung sounds were heard in 12 of the 117 (10%) workers in the 1975 study. Five had rales, one a pleural rub, two had coarse rhonchi suggestive of colds, and four had minimal changes that were considered transitory. For the whole 1975 group, the average FEV 1 was slightly less, and the average FVC was slightly greater than expected: FEV 1 was 96.6% of the expected value and FVC was 103.0% of the expected values. The ratio of % predicted FEV 1 to % predicted FVC was 75.8%. Wegman et al believed that these findings suggested some factor was affecting FEV 1 in the study population.

The authors [57] also found that TLC, RV/TLC and % predicted MMEF decreased as duration of employment in talc operations increased. The authors used stepwise multiple regression to assess the influence of exposure to talc and additional factors on FEV 1 and FVC. In the cross-sectional analysis of data from the 1975 survey, equations using age, height, years smoked, and years employed as independent variables explained 58% of the variation in FEV 1 and 52% of the variation in FVC. For FEV 1, the coefficients for age, height, and years smoked were statistically significant ($P<0.05$) and accounted for decreases of 20.7, 49.4, 20.2 ml/year, respectively. The coefficient for

WCD 001097

years employed in talc operations accounted for a decrease of 10.5 ml in FEV 1
each year, but the coefficient was not statistically significant at the 0.05
level (P=0.12). Since the P value approached statistical significance, the
authors suggested that the small number of individuals in the study and the
high degree of correlation between years of exposure to talc with other
factors that influence FEV 1, such as years smoked and age, would probably
have accounted for the lack of statistical significance for the years of
employment coefficient. Asa, the only statistically significant (P<0.025)
coefficient for FVC, accounted for a decrease of 69.2 ml each year.

Wagner et al [57] attempted to differentiate the effects of smoking and
exposure to talc by comparing their findings with those of other studies on
the effects of smoking on lung function. Workers exposed to talc for 20 or
more years had smoked an average of 10 years less than those exposed to talc
for less than 5 years. They found that FEV 1 decreased from 101.4% of the
predicted value in men exposed to talc for less than 5 years, to 87.6% in men
exposed for 20 or more years.

Using the mean FEV 1 of 3.61 liters for the study population, the
difference between 101.4% and 87.9% of FEV 1 was 490 ml [57]. According to
Wagner et al, measurements of FEV 1 generally decrease by about 10-17 ml for
each year of cigarette smoking. Thus, differences in cigarette smoking would
account for only 150-206 of the 490-ml difference in FEV 1 between the talc
workers employed for <5 and for >20 years (31-42%). Since FEV 1 was 104.6% of
the predicted value in the 26 talc workers who had never smoked and 97.3% in
former smokers, the authors suggested that workplace exposure to talc in the

WCD 001098

absence of cigarette smoking did not affect lung function, but that talc and cigarette smoke may interact, causing FEV 1 to decrease more than would be expected from cigarette smoking alone.

In the 103 workers studied in both 1975 and 1976, FEV 1 decreased by an average of 0.084 liter (SD=0.283) and FVC decreased by an average of 0.047 liter (SD=0.177) each year [57]. The differences between the 1975 and 1976 readings were not statistically significant.

Between 1975 and 1976, FEV 1 measurements decreased by an average of 15 ml/year in workers exposed to talc who had never smoked, by 40 ml/year in former smokers, and by 60 ml/year in current smokers [57]. When smoking histories of workers exposed to talc were compared with their current geometric mean dist exposures, the differences in exposures were small and in the same direction as smoking habits (nonsmokers were exposed at an average of 1.57 mg/cu m of respirable talc dust, former smokers at 1.75 mg/cu m, and current smokers at 1.91 mg/cu m). However, variations between current exposure levels, smoking histories, and changes in FEV 1 were apparently quite substantial, so that decreases in FEV 1 could not be related to current exposure levels. Using stepwise multiple regression, neither smoking histories nor current exposures were significant predictors of changes FEV 1. The authors suggested that this population be followed for a longer spread of time, perhaps 3 years, to determine reliably the effect of current exposure to talc on lung function.

Of the 78 workers from the 1975 study with readable chest X-ray films, 42 (54%) did not have any positive findings indicative of pneumoconiosis [57].

WCD 001099

Those with small rounded or irregular opacities present at a profusion of 1/1 or more generally had lower lung function values than did those with readings of less than 1/1, but the authors indicated that the differences were not statistically significant.

Weiman et al [57] concluded that lung function had been impaired in these workers as a result of workplace exposure to talc that did not contain free silica. They suggested that history of exposure to talc, as indicated by number of years employed, and smoking history, as indicated by number of years smoked, seemed to be of the same magnitude of importance in predicting FEV 1 in workers exposed to talc after correction for age and height. Lung function was apparently not affected in workers exposed to talc who had never smoked, but further longitudinal studies are needed to verify this preliminary finding. Finally, estimates or indices of past exposures based on measurements of current exposures were not well correlated with changes in lung function as measured by changes in FEV 1.00 Many investigators have studied the health of workers from the State of New York who were exposed to talc with or without asbestiform minerals such tremolite, anthophyllite, and chrysolite.

A study in which signs and symptoms of respiratory disease in miners and millers of an asbestiform talc were compared with those in miners and millers of a nonasbestiform talc was reported by Wagner et al [58] in 1959. Included in the study were 238 workers exposed to asbestiform talc in two operations in St. Lawrence County and 61 workers exposed to nonasbestiform talc in an operation in Lewis County. Medical and occupational histories were obtained,

WCD 001100

and physical examinations, including a chest roentgenogram, were performed, although information on the procedures or the diagnostic criteria used was not provided. The findings are presented in Table III-4.

TABLE III-4

SIGNS AND SYMPTOMS OF RESPIRATORY DISEASE IN WORKERS EXPOSED TO ASBESTIFORM AND NONASBESTIFORM TALC

	Asbestiform Talc*		Nonasbestiform Talc	
	Mine	Mill	Mine	Mill
Respiratory symptoms	48%	37%	40%	33%
Positive lung findings	35%	25%	20%	22%
Limited chest expansion	35%	48%	40%	29%
Fibrosis (X-ray)	3.6%	12%	0	4.3%
Number of workers	82	356	15	46
Av age (yr)	39.3	42.3	36.9	37
Av length of exposure (yr)	12.7	13.0	10.3	12.3
Av dust concentrations**				
Before controls (mppcf)	120-818	69-1,227	-	171-199
After controls	3-4	11-52	1-5	23-66

*Operations in Lewis County, New York. Ore also contained asbestiform minerals and about 5% free silica.
**Operations in St. Lawrence County, New York. Ore also contained about 1.4% free silica.
***Total dust as SiO2. Engineering controls implemented in 1968 in asbestiform talc operations and in 1970 in nonasbestiform talc operations.

Adapted from Kassabe et al [58]

WCD 001101

Percentages of workers with respiratory symptoms, limited chest expansion, and positive lung findings, i.e, auscultatory sounds, were similar in all four groups (58). In contrast, the percentage of workers with roentgenographic evidence of pulmonary fibrosis was greatest in asbestiform talc millers (12%), followed by nonasbestiform talc millers (4.3%) and asbestiform talc miners (3.6%). None of the 85 miners exposed to asbestiform talc had evidence of pulmonary fibrosis. The chest roentgenograms of miners exposed to asbestiform talc showed bilateral reticulation and fibronodular infiltrations in the mid- lung and lower lung areas. The chest X-ray films of millers exposed to asbestiform talc showed "bronchovesicular markings, reticulation, granularity, and, in some cases, discrete nodulation (58)." One miller had a plaque containing talc, another had a coalescence of nodules, and a third had emphysematous bullae. Roentgenographic findings in millers exposed to nonasbestiform talc were limited, in two cases, to increased bronchovesicular markings. The authors also stated that evidence of pulmonary fibrosis was not found in millers who were exposed to either asbestiform or nonasbestiform talc who had been employed <10 years and had been exposed at <20 mppcf of dust, but supporting data were not presented. This study indicates that exposure to both asbestiform and nonasbestiform talc with 5 and 27% free silica, respectively, is associated with the development of pulmonary fibrosis, although the frequency and severity of the changes appear to be greater in asbestiform than in nonasbestiform talc workers.

Lung function measurements and signs and symptoms of respiratory disease in workers exposed to asbestiform talc were compared with those in workers

WCD 001102

exposed to nonasbestiform talc by Kleinfeld et al (40) in 1964.

The 30 asbestiform and 13 nonasbestiform talc workers included in the study had been exposed to talc dust for at least 10 years (40). The two groups were comparable in all aspects but sample size. The average age of the 30 asbestiform talc workers was 49.4 years, they had worked an average of 19.5 years, and 59% of them had smoked 20 or more cigarettes daily for at least 5 years. For the 13 nonasbestiform talc workers, the average age was 51.4 years, and they had been employed an average of 17.9 years, and 54% of them had smoked. Average concentrations of airborne dust at which workers were exposed were 62.1 mppcf (10.5 mg/cu m) for workers exposed to asbestiform talc and 62.7 mppcf (10.4 mg/cu m) for workers exposed to nonasbestiform talc.

Each worker was asked about the presence of respiratory symptoms and was given an examination that included measurements of lung function and a roentgenogram (40). Labored breathing was experienced during exertion by about one-half of both the asbestiform (53%) and the nonasbestiform talc millers (46%) (40). Two asbestiform talc workers had labored breathing while at rest. Abnormal auscultatory sounds, eg, rales, rhonchi, and wheezing, were heard in 27% of the asbestiform talc workers and in 46% of the nonasbestiform talc workers.

Roentgenographic evidence of pulmonary fibrosis was found in 43% of the asbestiform talc workers and in 23% of the nonasbestiform talc workers. Thus, the prevalence of roentgenographic changes indicative of fibrosis was greater in asbestiform than in nonasbestiform talc workers, but the other indicators of respiratory disease were equivalent (labored breathing) or greater

WCD 001103

(auscultatory sounds) in nonasbestiform than in asbestiform talc millers.

Most lung function measurements were lower than normal in both asbestiform and nonasbestiform talc millers (40). Vital capacity was 23.4% lower than normal in asbestiform talc millers and 13.8% lower in the nonasbestiform talc millers, and the difference between the two percentages was statistically significant ($P<0.05$). Similarly, the percentage decrease from normal values of vital capacity at 1 second, maximum breathing capacity, and total lung capacity was slightly greater in asbestiform talc workers than in nonasbestiform talc millers. The authors reported that the correlation was poor between the extent of exposure to talc dust and the degree of impairment of lung function. In addition, correlations were not consistent between the extent of lung function impairment and the degree of labored breathing or the extent of roentgenographic changes indicative of pulmonary fibrosis.

The authors (40) concluded that, in certain individuals, prolonged exposure to nonasbestiform talc can produce pulmonary fibrosis similar to that associated with prolonged exposure to asbestiform talc. Based on roentgenograms and measurements of lung function, they strongly suggested that respiratory changes associated with exposure to asbestiform talc occurred more frequently, and were more severe, than those associated with nonasbestiform talc. Their data indicated, however, that auscultatory signs indicative of respiratory disease occurred more frequently in nonasbestiform than in asbestiform talc workers, and that the percentages of workers with labored breathing in the two groups were equivalent. Since there is little correlation between the signs and symptoms of respiratory disease, further

WCD 001104

studies are needed to determine appropriate indices of respiratory impairment.
The study indicates, however, that exposure at about 60 mppcf (10 mg/cu m) to asbestiform or nonasbestiform talc is associated in some workers with the development of labored breathing, auscultatory sounds, impairment in lung function, or roentgenographic signs of pulmonary fibrosis, and that these changes are often not correlated well with each other.

Dement et al [59] of NIOSH recently reported extensive studies of the health of workers who mined or milled asbestiform talc. The physical and chemical characteristics of the talc were studied and concentrations of airborne talc were compared to signs and symptoms of chronic respiratory impairment in actively-employed workers. In addition, the distribution of deaths in talc workers from various causes were compared with the distribution in the general population.

In the morbidity study, Dement et al [59] analyzed the signs and symptoms of chronic respiratory impairment in miners and millers exposed to asbestiform talc. Of the 156 men employed at the one plant studied, 121 (78%) participated in the study, and their average duration of employment was 10.2 years.

Measurements of lung function, symptoms of respiratory disease, and roentgenographic findings of pneumoconiosis in workers exposed to asbestiform talc were compared with findings from similar NIOSH studies of chronic respiratory impairment in 9,347 coal miners and 1,095 potash miners [59]. Since virtually the same procedures were used to analyze health effects in the three studies. Workers exposed to asbestiform talc had similar confounding

WCD 001105

variables with coal and potash miners than with salaried workers exposed to asbestiform talc or local population. These potentially confounding variables included physique, socioeconomic status, education, and nutrition. Also, the extent of respiratory disease in workers exposed to talc with asbestiform minerals could be assessed relative to the extent of disease in two other groups of workers. Numerous studies have found that exposure to coal in the workplace can impair respiratory function, but, according to the authors, a few studies have indicated that exposure to potash does not increase the prevalence of respiratory disease. Thus, differences in these measurements between potash and talc workers in indices of chronic respiratory impairment were more likely to have reflected the effects of exposure to asbestiform talc than were differences between talc and coal workers.

For purposes of comparison, findings for coal and potash workers were adjusted by age (10-year intervals), by height (10-cm intervals), by smoking history (current, former, or never), and by years of employment (<15 years * 15 years) to the distribution of these variables in the group of 121 talc workers.

In general, the prevalences of cough and phlegm were greater in talc workers than in coal or potash workers (59). For the 30 talc workers employed <15 years, the prevalences of cough and of phlegm were significantly greater than in coal or potash workers. For the 31 employed in talc operations for 15 or more years, the prevalence of cough was still significantly greater than in potash miners, but about the same as in coal miners. The prevalence of phlegm was about the same in potash and talc miners employed for 15 or more years,

WCD 001106

but was significantly greater (P<0.0) in coal miners than in talc workrs.

Differences in the prevalence of roentcenographic abnormalities between the three groups and by length of employment in talc operations were more substantial than were differences in respiratory symptoms. In workers employed for <15 years, the prevalence of roentcenographic abnormalities was 12% for all three groups of workers combined. Pleural thickening (grade 1 or 2) was found in 1.2% (1 or 2) of the talc workers, but in only 0.3% of the coal miners employed <15 years. In contrast, 68% (13 of 39) of the talc workers employed 15 or more years had evidence of pleural thickening, compared with 1.5% of the coal miners and 3.7% of the potash miners. Both differences were statistically significant (P<0.05). Pleural thickening showed no association with cigarette smoking and was not found in workers younger than 40 years of age. None of the talc workers employed <15 years had roentgenographic evidence of pleural calcification, but the prevalence in both coal and potash workers was so small that the differences could not be evaluated statistically. Four of the talc workers (10.3%) employed 15 years or more had evidence of irregular opacities on their chest X-ray films, compared with 5.8% of the coal miners and 2.6% of the potash miners (P<0.005). One talc worker employed 15 or more years had a regular opacity (2.6%), compared with 14.3% of the coal miners and 1.6% of the potash miners. For the 93 talc workers with no previous workplace exposure to talc, the findings were usually in the same direction as those for the 121 talc workers, but only one finding was statistically significant. Evidence of pleural thickening was found in 3% of the talc workers employed only at the plant under study but in

WCD 001107

only 1.5% of the coal miners (P<0.05) and 4.4% of the potash miners (P<0.05) employed for 15 or more years.

Most measurements of pulmonary function, including FEV 1 and FVC, were lower in talc workers than in coal or potash workers [59]. For the 121 talc workers, the mean FEV 1 was 6% less than the predicted values based on measurements in both coal miners and potash miners. Mean FVC's for the 121 talc workers were 6 and 8% less than predicted, based on values for potash and coal miners, respectively. For talc workers, reductions in % predicted FEV 1 and FVC were significantly associated with estimates of cumulative exposures to both asbestiform fibers and particulates. For 100 fiber-years/cc of exposure, % predicted FEV 1 in workers exposed to asbestiform talc decreased by 10.3%, compared with coal workers (SD=3.0%, P<0.001) and by 14.4%, compared with potash workers (SD=3.1%, P<0.0001). Percent predicted FVC decreased by 11.0% compared with coal (SD=2.6%, P<0.001) and by 14.7% compared with potash workers (SD=2.8%, P<0.001)/100 fiber-years/cc of exposure. Decreases in % predicted FEV 1 and FVC/10 mg of particulate-years/cu m were about half the magnitude of the decreases/100 fiber-years of exposure. For each 10 mc of particulate-years/cu m of exposure, % predicted FEV 1 in the 121 workers decreased by 3.8% compared with coal miners (SD=1.8%, P<0.05) and by 6.2% compared with potash miners (SD=1.9%, P<0.005).

Since evidence of pleural thickening was the major roentgenographic finding of the study, Dement et al [59] compared information on symptoms, pulmonary function, and exposure in workers with grade 1 or 2 pleural thickening with information for unaffected talc workers. In talc workers 50-

WCD 001108

55 years of age who had been employed for 15 or more years, the prevalences of
2373 cough and phlegm were significantly greater in workers with grade 2 pleural
2374 thickening than in unaffected workers. However, the prevalences of these
2376 symptoms were significantly lower in those with grade 1 pleural thickening
2378 than in unaffected workers. Cumulative exposure to fibers was somewhat
2379 greater in talc workers with pleural thickening than in unaffected workers,
2380 although average yearly exposures were similar for the two groups. Cumulative
2382 exposures to particulates were actually slightly lower for affected than for
2383 unaffected workers, and there were no differences in cigarette smoking habits
2384 between the two groups of talc workers. In talc workers 40-60 years of age,
2385 those with pleural thickening had begun to work at an earlier age and had
2386 lower % predicted FEV 1 and FVC than did unaffected workers.
2391 Dement et al [59] indicated that the prevalence of respiratory symptoms
2392 seemed to be greater in workers exposed to asbestiform talc than is usually
2393 found in relatively healthy populations. The authors made a rough comparison
2394 of the signs and symptoms of respiratory disease in miners and millers exposed
2396 to asbestiform talc with those in miners and millers exposed to chrysotile
2397 [59] and in cotton millers [59]. In current and former smokers, the
2399 prevalences of cough and phlegm in talc workers were similar to those in
2400 chrysotile workers and approximately two or three times greater than those
2401 found in cotton millers. The prevalences of roentgenographic evidence of
2402 pneumoconiosis and pleural calcification was similar in workers exposed to
2404 chrysotile and to asbestiform talc, but the prevalence of pleural thickening
2406 was quite different in the two groups. In workers over 35 years of age, 29%

WCD 001109

of the miners and millers exposed to asbestiform talc has pleural thickening, compared with 5% of the workers exposed to chrysotile (P<0.01).

In conclusion, this study [59] has shown that actively employed workers exposed to talc containing anthophyllite and tremolite had increased prevalences of cough and phlegm and of signs of respiratory impairment, including reduced FEV 1 and FVC, and that after 15 years of employment, nearly one-third of the workers had evidence of pleural thickening.

Dement et al [59] also studied the mortality of workers who had been employed at the same mine and mill in New York where they had conducted the morbidity study discussed above. All men first employed at the mine or mill between 1947 and the end of 1959 were included in the study, and the vital status of the workers was determined as of June 30, 1975. Of the 398 workers included in the study, 50% (202) had worked at the mine or mill for <1 year, 23% (90) for 1-10 years, and 27% (106) for >10 years. By the end of the study period, 74 (19%) of the workers had died, 308 (77%) were known to be alive, and the status of 16 (4%) was not known. The 398 workers had accumulated a total of 8,782 person-years at risk of death between 1947 and 1959. The expected number of deaths from various causes was estimated from the years at risk and the appropriate age- and time-specific death rates for white men in the United States. The results are summarized in Table III-5 [59].

TABLE III-5

DEATHS IN MINERS AND MILLERS OF ASBESTIFORM TALC FROM ST. LAWRENCE COUNTY, NEW YORK

WCD 001110

TALC FIRST DRAFT

Cause of Death	Observed	Expected	O/E
Cancer	19	10.5	1.8*
Respiratory	10	3.2	3.1
Digestive	4	2.9	1.0
Lymphatic and haematopoietic	4	1.3	3.1
Other	1	3.1	0.6
Nonmalignant respiratory disease	11	3.37	3.3
Tuberculosis	1	0.57	1.8
Pneumoconiosis	5	1.4	3.6
Influenza and pneumonia	3	1.4	2.1
Heart disease	26	25.6	1.0
Accidents	10	6.7	1.5
Other causes	8	16.4	0.49
All causes			

*P<0.05 is underlined

another nonmalignant respiratory diseases

Adapted from Damant et al 1991

WCD 001111

In workers exposed to asbestiform talc the O/E ratio of death from cancers of the respiratory system was 3.1** (17 observed, 5.2 expected, P<0.01), with 9 of the 10 deaths from cancer of the bronchus or lung (2.9 expected, P<0.01) (59). The average latent period between first employment at the talc plant under study and death from cancer of the respiratory system was 19.0 years (SD=5.9), and the average age at death for the 10 workers was 56.4 years (SD=10.7). The authors found that the O/E ratios of death from lung cancer increased as the length of the latent period beginning with first employment increased. No deaths from lung cancer were observed within <10 years of first employment in the talc mine or mill (0.5 expected), and the O/E ratios of death were 2.1** within 10-19 years of first employment (3 observed, 1.4 expected), and 5.5** within 20-28 years of first employment (6 observed, 1.1 expected, P<0.01). Three additional workers in the study died of lung cancer, but these deaths were not included in the tabulations, since they occurred after June 30, 1975, the end of the followup period.

The O/E ratios of death were elevated for influenza and pneumonia, respiratory tuberculosis, COPD, and all nonmalignant respiratory diseases; all but the first were significantly elevated (P<0.05) (59). For the five who died of COPD, the average age at death was 59.8 years (SD=9.4), and the duration of employment at the talc plant ranged from less than 1 month to 14 years (average=7.0 years, SD=6.2 years). Information on previous occupations was available for two of the five, but one having worked in a limestone quarry for 9 years and the other in another talc operation in New York for 5 years.

The observed number of deaths from heart disease and from cancer of the

WCD 001112

digestive system were nearly identical to the expected values. The O/E ratios
for cancer of the lymphatic and haematopoietic tissues and for accidents were
elevated, although not statistically significant.

Dement et al [59] concluded that workers employed at this talc mine and
mill had an excessive risk of mortality from lung cancer and from nonmalignant
respiratory disease. Workers at this plant were exposed to talc containing
tremolite and anthophyllite, but little free silica. The authors believed that
tremolite and anthophyllite were probably the prime etiologic agents
associated with the increase in respiratory cancer and nonmalignant
respiratory disease in these talc workers. Dement et al related that numerous
epidemiologic studies [60,61,62] had shown that Finnish workers exposed to
anthophyllite had an increased risk of developing lung cancer. However, no
cases of mesothelioma were reported in any of these studies. Since the one
worker in this study [59] who developed mesothelioma had also worked in the
construction industry, where he could have been exposed to other types of
asbestiform minerals, Dement et al did not attribute this case to exposure to
tremolite or anthophyllite. They suggested, however, that the possibility
that exposure to tremolite or anthophyllite could cause mesothelioma be
studied further. The authors noted that four of nine workers who died of lung
cancer had worked at the talc plant studied for <1 year. Only one had worked
at another talc plant and for only 5 months. The authors indicated it was
plausible that brief exposures at elevated concentrations of asbestiform
minerals might be associated with an increased risk of developing lung cancer
and noted that one such observation had been previously reported [59]. In a

WCD 001113

study of mortality in workers exposed to Vermont talc that did not contain
asbestiform minerals. Selevan et al [52] found that miners but not millers had
an increased risk of developing lung cancer. Like Dement et al [59], Selevan
et al [52] found that, for talc workers who died of lung cancer, the durations
of employment in the mines varied considerably, and that some were relatively
short. Dement et al [59] did not determine whether the lung cancer risk was
greater in miners or millers exposed to asbestiform talc, but it is of
interest that both studies showed wide variations in the duration of exposure
to talc alone or asbestiform talc for workers who died of lung cancer.

A study of mortality in workers exposed to asbestiform talc, first
reported in 1967 [63], was updated by Kleinfeld et al in 1974 [64]. Workers
were exposed to a talc that contained 2-5% free silica and were employed in
mines and mills.

Included in the study were 260 workers who either were exposed for at
least 15 years between 1940 and 1969 or were employed in 1940 and had
previously been exposed to talc dust for at least 15 years [64]. Many sources
of information were reviewed by the authors, including death certificates and
records of the companies, appropriate hospitals, private physicians, and of
the state industrial hygiene department. They found that 198 of the 260 talc
workers (62%) had died between 1940 and 1969. The average age at death was
60.3 years (range 38-84 years), and the average duration of exposure to talc
dust was 24.1 years (range 15-47 years). The percentage of deaths from
cardiac diseases and from cancer of the respiratory and digestive tracts in
these workers exposed to talc was compared with the percentages of deaths from

WCD 001114

these causes among white men in the United States in 1955, the median year for
2585 the 19% deaths.

2587 Thirteen workers exposed to talc died of malignancies of the respiratory
2588 system, 12 from carcinoma of the lungs, and 1 from fibrosarcoma of the pleura
2589 [64]. Thus, 12% of the talc workers died of respiratory malignancies,
2590 compared with 3.7% of United States white men in 1955; the more than threefold
2592 difference between the percentages is statistically significant (P<0.05).
2593 Eight of the 108 talc workers (7.4%) died of cancer of the gastrointestinal
2594 tract compared with 6.5% of the general population (P>0.05), and 27.8% of the
2595 talc workers died of cardiac disease compared with 45.8% of the controls
2597 (P<0.05). Twenty-nine talc workers died of pneumoconiosis or its
2598 complications, 20 from cor pulmonale, 5 from advanced tuberculosis, and 4 from
2600 bronchopneumonia. The percentage of men in the general population who died of
2601 nonmalignant respiratory disease was not reported, but the study suggests that
2602 workers exposed to asbestiform talc were more likely to die of either
2603 malignant or nonmalignant diseases of the respiratory system than was the
2605 general population.

2607 Precise estimates of the risk of developing malignant or nonmalignant
2608 respiratory disease in workers exposed to asbestiform talc were not provided
2609 by this study [64]. The procedures used to identify deaths of talc workers
2611 were not discussed in sufficient detail, and the smoking history of the
2612 population was not investigated. Information on causes of death in the general
2613 population was taken from death certificates, and if similar information on
2615 workers exposed to talc were obtained from sources other than death

WCD 001115

certificates, the comparison between these two groups might not be adequate.

In addition, the distribution of deaths in the mineral population in 1955 may not have reflected the distribution of deaths in the 30-year period from 1940 to 1969. The decrease in the percentage of deaths in workers exposed to talc from heart disease may have been related to increases in the percentages of deaths from other causes such as malignant and nonmalignant respiratory disease, rather than to an actual decrease in the risk of death from heart disease. The authors believed that deaths from lung cancer would have occurred less frequently in workers employed after 1945, when concentrations of airborne talc were reduced in both the mines and the mills. Although a reasonable assumption, the data presented by the authors are not sufficient to support this conclusion. Since the average duration between first exposure and death from respiratory cancer was 24 years, few workers first employed after 1945 could have died of respiratory cancer before the end of the study period in 1969. Although the estimate is imprecise, the threefold increase in deaths from respiratory cancer is of sufficient magnitude to indicate that this finding is not an artifact. It appears from this study therefore that workplace exposure to asbestiform talc can increase the risk of developing cancer of the respiratory system.

WCD 001116

WCD 001117

Animal Toxicity

Experiments with animals have shown that talc can produce similar effects on animals as seen on humans occupationally exposed to talc.

Bethke-Iwanska [05], in 1977, published results from a study on 2-month-old male rats (weighing 130-170 g) exposed to what was described by the author only as "technical" grade and "pharmaceutical" grade talcs. Two groups of 35 rats were exposed to each grade of talc in a chamber for 6 hours/day for 6 days/week for 9 months. Fifteen control animals were kept in separate talc free chambers. Dust concentration in the chambers was determined by a gravimetric method. The average dust concentration in the chambers from the time talc was introduced to 60 minutes later was 346- 30 mg/cu m (2,016-180 mppcf) for technical talc, and 383-31 mg/cu m (2,208-138 mppcf) for pharmaceutical talc. The particle size range for the talcs tested was between 1 and 5 fu/m.

After 7 days, 14 days, 3 months, 6 months and 9 months, seven rats from each of the exposed groups and three rats from the control group were killed and the pulmonary systems were examined through autopsy [05]. No changes were reported in the group exposed for 7 days, but gross examinations of the other groups showed the following pronounced changes in the respiratory tract. After 14 days of exposure, microscopic examinations showed that both groups of animals had developed nonspecific inflammation in the respiratory tract, and after 6-9 months, the inflammation in the larynx, trachea, and bronchi was

considered chronic and atrophic. In the lungs of both groups of animals, talc
dust caused a fibrocellular reaction that produced a focal fibrosis and
emphysema. Another granulomatous cellular reaction was observed in the
lymphatic nodes. After 3 and 6 months of exposure, the animals had phagocytes
in the alveolar lumina. These phagocytes later formed cellular nodules which
developed into fibrocellular nodules after 9 months. In addition, the
investigator noted that, as the pulmonary arterial walls thickened, the lumina
narrowed. These changes were present in both groups of exposed animals but
not in the control group.

The authors [65] concluded that both technical and pharmaceutical grade talc dusts produced pronounced changes throughout the respiratory system at the concentration at which these animals were exposed, and that both grades of talc induced similar respiratory changes which increased in severity as the duration of exposure increased.

Wehner et al [66] exposed groups of 4-week-old male and female hamsters to an aerosol of cosmetic grade talc characterized as 95% platy pure talc with trace quantities of carbonates and platy chlorite for periods of 3, 30, and 150 minutes/day for 30 days and 7-week-old male and female hamsters for 30 or 150 minutes/day for 300 days (or until death). The mean total aerosol concentrations were 37.1 ±1.4 (SD) mg/cu m and 27.6 ±3.4 (SD) mg/cu m, respectively, and the mass mean aerodynamic diameter of the respirable fraction was 6 [mu]m. Control animals were kept in identical rooms with identical food, temperature, and humidity and were handled in the same manner by being transferred to a similar exposure chamber for the specified period of

WCD 001118

time to simulate the stress of handling (but exposed to filtered room air
2710 rather than talc aerosol). Animals were kept for observation until 90% of the
2712 group had died naturally, at which time the survivors of the group were
2713 killed.

2715 The authors [66] found no significant effect of exposure at these
2716 concentrations or durations on body weight, lifespan, or the type, incidence
2717 or severity or lesions observed in post mortem examinations. An increase was
2719 found in the incidence of alveolar cell hyperplasia, histocytosis and
2720 interstitial pneumonia in females with increasing exposure concentrations. The
2722 widespread occurrence of interstitial pneumonia in both exposed and control
2723 animals (48% in controls, 62% exposed animals) makes interpretation of this
2724 study difficult but it appears that the exposure level of this experiment may
2725 be near the minimum required to produce an observable effect in this species.
2728 The increasing incidence of lesions in exposed females suggests that further
2729 study is necessary concerning a potential sex difference in risk.

2732 Schepers and Durkan [67] also conducted a series of experiments using
2733 various combinations of tremolite, anthophyllite, serpentine, quartz, and pure
2734 talc.

2736 In one experiment, Schepers and Durkan [67] injected intratracheally a
2737 total dose of 100 mg of talc dust (3 fibs or less in diameter, contaminating
2738 substances removed by sedimentation in liquids) into 12 adult guinea pigs.
2739 Microscopic examination of the lungs at necropsy revealed irregularly
2740 distributed confluent pneumonic patches with talc-containing macrophages after
2742 1 month. In 1-2 years, surviving animals developed bronchiolectasis,

WCD 001119

bronchitis, perivascular and peribronchial cellular proliferation and
fibrosis, and fibrocellular pleural sclerosis.

Schepers and Durkan (1971 reported that six guinea pigs, injected intratracheally with a 75-mg mixture of 75% talc and 25% quartz, developed multiple fibrocellular granulomas, bronchiolitis and bronchiolectasis, perivascular fibrocellular reactions, periadenitis, and lymphoid hyperplasia after 1 year.

When a 75-mg mixture of 50% talc and 30% tremolite, and 20% anthophyllite of (20-50 tube was injected intratracheally into six guinea pigs, subpleural, peribronchiolar, and perivascular macrophages and fibrocytic proliferation were seen within a year (971. A dust mixture containing 43% talc, 36% tremolite, (30(m or less) and 14% quartz and 17% anthophyllite (20-50 tube, induced massive exuberant macrophage and fibrocytic cellular proliferation, bronchiolectasis, and bronchitis with minimum fibrosis in six guinea pigs after 1 year.

Among the other dust minerals tested separately by Schepers and Durkan (971, serpentine was found to result in chronic bronchitis and bronchiolectasis. The authors concluded that tremolite and anthophyllite exhibited their maximum fibrogenic effect when the fibers used were 20-50 (m in length and only the tremolitic mineral with long fibers produced a marked, fibrocellular, diffuse pneumonitis with tremolite bodies. This study shows that talc induces a macrophagic response and fibrosis with and without the presence of free silica or asbestos. The authors concluded that presence of asbestos minerals with long fibers resulted in more rapidly developing lesions

WCD 001120

of greater severity than with talc alone.

Gross et al [68] investigated pulmonary responses of rats exposed to two different talc dusts containing tremolite, fibrous quartz and chrysotile asbestos. One talc dust had high natural nickel content and contained fibers with an average diameter of 0.2 fu/m. Another dust had a low nickel content and a fiber diameter of 0.1 fu/m. Each dose was given to 25 rats by intratracheal injection in a single dose of 25 mg. Four rats from each group were killed 4 days after injection; the rest were examined when they died.

Four days after the rats were injected, the lungs of all the rats examined were found to have polypoid proliferative acute inflammation involving small bronchi and bronchioles [68]. Within a few months, the initially erysipelitic stroma was converted into dense collagenous scars that often deformed the bronchi and bronchioles. The authors found similar proliferative, nonreversible lesions to be produced by both talcs, quartz and chrysotile.

Because of the case reports discussed previously implicating talc as the main irritant in the formation of granulomas and adhesions in surgical patients, Gerson [69] conducted a series of experiments to study the relationship between talc and the etiology of granulomas in animals. Rabbits and guinea pigs were used, and talc of the type used surgically in the form of sterilized dry powder or in saline solution was introduced ip or through laparotomy, with or without additional traumatization.

In one experiment, four female rabbits received talc suspension in physiological saline administered ip [69]. In two killed at 18 and 24 hours,

WCD 001121

agglomerations of talc were found attached to the peritoneal wall, and the
2815 peritoneal cavity contained a small amount of yellowish, cloudy liquid that
2816 had macrophages with minute crystals. No adhesions were found, nor were there
2818 any polynuclears or exudate of fibrin. The other two rabbits were killed 4
2819 weeks after being injected. No adhesions or exudates were found, but there
2821 were a few yellowish granulomas in the large intestine and omentum.
2823 Microscopically, these granulomas were covered with intact layers of serosal
2824 cells and contained talc particles.

2827 In other experiments dry talc or talc in saline suspension was introduced
2828 by laparotomy into rabbits in some of which the splanchnic organs were
2829 mechanically abraded [69]. The dry talc was found to produce more granulomas
2830 than the talc suspension, and adhesions were found only in those animals whose
2832 organs had been abraded. Control animals who also had been abraded showed
2833 similar adhesions but no granulomas.

2835 From these experiments, Gerean [69] concluded that, once talc was in the
2836 abdomen, it was immobilized and covered by serosal cells without formation of
2837 an exudate and adhesion as long as there was no injury to the peritoneum.
2839 Adhesions developed only with traumatization and exudate of fibrin. In such
2841 cases, talc was caught up in the fibrin and incorporated into the adhesions,
2842 thus increasing the bulk and density of granulomas and impeding the resolution
2843 of adhesions.

2846 Saxon and Yuceisan [70] also conducted a similar experiment on rats and
2847 found that trauma and injury to the tissues were additional factors for the
2848 formation of talc granulomas. In addition to using rabbits, guinea pigs, and

WCD 001122

rats, Graham and Jenkins [71] also applied talcum powder to the peritoneal cavity and to skin wounds of kittens and mice. Fifty milligrams of talcum powder produced severe adhesions and marked granulomas in the peritoneal cavities of these animals within 6-8 weeks. When 10 mg of talc powder was applied to skin wounds, similar adhesions and granulomas were seen as in the peritoneal cavity, although the rabbits and mice were less severely affected. This supports the observations concerning skin granulomas in humans by Tye et al [45].

Body distribution and elimination in animals exposed to talc by various routes has also been reported by several authors.

Wehner et al [72] performed tests with hamsters in which they determined the pulmonary deposition, translocation, and clearance of inhaled irradiated cosmetic grade talc characterised in a previous experiment [66]. In the experiment, 10-week-old hamsters were given a single 2-hour exposure to irradiated talc. Exposure took place only through the nose. Over the next 4 months, groups of four hamsters each were killed and their bodies examined by gamma ray spectroscopy to determine the location of talc remaining in them.

The authors [72] found that 6-8% of the inhaled talc was deposited in the alveoli the biologic half-life of this talc was 7-10 days, and it was essentially gone at the end of 4 months. No translocation to the liver, kidneys, ovaries, or other parts of the body from the gastrointestinal tract was found. They also mentioned briefly that pc quantities of $^{60}Co found in the urine probably resulted from the leaching of $^{60}Co of talc in the gastrointestinal tract.

WCD 001123

In a similar study, Phillips et al.[73] examined both the distribution and absorption of tritiated pharmaceutical talc in rats, mice, and guinea pigs by the oral route. Three male rats were given a single dose of talc by oral intubation, three male rats were given oral doses daily for 6 days, three female guinea pigs were given a single oral dose, and four female mice were given a single oral dose. Urine and feces were collected at 24-hour intervals, and all animals were killed after 10 days. The results showed 95.2 and 94.4% recovery of the labeled compound from the feces of rats and guinea pigs, respectively, after 96 hours. In mice, virtually 100% of the labeled compound was found in either the gastrointestinal tract or in the feces with less than 0.005% detected in the remaining carcass. Less than 2% of the labeled compound was found in the urine in any of the species examined, and the authors attributed the trace 3H label that was found in the urine to most likely to be due to contamination of samples within the metabolism cages. The study showed that orally administered talc was not absorbed from the gastrointestinal tract to any appreciable extent and that it is almost entirely excreted in the feces over a period of 3-4 days.

Wehner et al [74] studied the absorption of talc ingested by hamsters. The cosmetic talc (characterized in a previous experiment) was first exposed to an integrated neutron flux, and, after 30 days, this neutron-activated talc was suspended in physiologic saline solution. The talc suspension was administered to six 10-week-old female Syrian golden hamsters by intubation; four others received a suspension of nonirradiated talc, and four received no talc. After 24 hours, the hamsters were killed and various tissue samples

WCD 001124

were analyzed by gamma ray spectrometry.

The data showed that, after 24 hours, approximately 75% of the ^{60}Co used as a tracer for talc was excreted in the feces, while approximately 23% was found in the gastrointestinal tract [74]. About 2% of the ^{60}Co label was found in the carcasses but the lungs, kidneys and liver did not differ significantly from the controls ($P>0.05$) in gamma ray counts. A trace (0.09%) of the radioactivity appeared in the urine, which the authors suggested might be explained by leaching of ^{60}Co from the gastrointestinal tract.

The results of Wehner et al [74] using hamsters as test animals appear to be in general agreement with those of Phillips et al [73], who used rats, mice, and guinea pigs. The intestinal absorption of talc was negligible (<2%) in all animals species studied. Whether the small amounts of ^{131}I and ^{60}Co found outside of the gastrointestinal tract and feces is artifactual or represents a trace amount of intestinal absorption has not yet been determined. However, the authors' speculations that this was due to a leaching of the label from the talc seems reasonable.

Few studies have been located which examine the carcinogenic, mutagenic, teratogenic, or reproductive potentials of talc.

In 1976, Pott et al [75] reported the tumorigenic effect of a variety of fibrous and granular dusts, including a nonasbestiform talc, introduced into the peritoneal cavity of rats as a suspension (25 mg/2 ml) in saline. The rats received the intrapleural injections up to four times/week, at intervals of 1 week. After injection, the animals were allowed to live out a normal life or were killed whenever they were moribund. At autopsy, gross and

WCD 001125

microscopic examinations were performed on tumorous tissues.

A visible amount of dust was observed in the abdomen of many rats [73]. On the average, the animals had a survival time of 602 days after injection. One rat developed mesothelioma after 587 days. The authors attributed the low frequency of tumor induction to the nonfibrous nature of the talc.

In 1973, Smith [76] reported the effect of asbestos and other minerals, including tremolitic talc, on male Golden Syrian hamsters. A group of 50 hamsters received a single ip injection of 25 mg of tremolitic talc. The composition of the tremolitic talc was fibrous tremolite (50%), antigorite (10%), talc (35%), and chlorite (5%). The talc was composed of 75 and 25% of the platy fibrous or rolled forms, respectivaly. The average length and diameter were 5.7 and 1.6 (um, respectivaly, for fibrous particles and the platy particles had a 2.0-(um diameter. The animals were allowed to live out a normal life span or were killed whenever they were moribund. Gross and microscopic examinations were performed on the organs and tissues.

Gross examination showed small depots containing round and giant cells on the lung surface. After 700 days, seven hamsters were alive, but were later killed for examination. Microscopic examination revealed no tumors or mesotheliomas. The author concluded that tremolitic talc was not carcinogenic and that it produced a less fibrogenic reaction than did chrysotile.

The mutagenicity of talc was evaluated for the US Food and Drug Administration in a battery of screening tests, including a host-mediated assay, cytogenetic tests, and a dominant lethal test [77]. In the host-mediated assay, mice were given talc orally in doses of 30-5,000 mg/kg, either

WCD 001126

as a single dose or divided into five equal daily doses. Dimethyl nitrosamine or ethyl methane sulfonate were used as positive controls. The animals were then injected ip with histidine-requiring mutants of Salmonella typhimurium or a diploid strain of Saccharomyces cerevisiae. After 3 hours, they were killed and the fluid from the peritoneal cavity was serially diluted and plated to determine mutation frequency. This test showed no significant increase in mutant colonies of Salmonella or recombinant colonies of Saccharomyces. In vitro mutagenicity testing of these microorganisms with talc also gave negative results.

In the cytogenetic studies, the investigators [77] examined bone marrow cells of rats given talc orally at 30-5,000 mg/kg in one or five daily doses and killed 6-48 hours after the last dose. Triethylene melamine was used as the positive control substance. Human lung cell cultures treated with talc in vitro were also examined. Neither of these tests showed any significant difference from control values in the number and type of chromosomal aberrations.

In the dominant lethal study, talc was administered orally to groups of 10 male rats at 30-5,000 mg/kg in single or divided doses [77]. Triethylene melamine was administered as a positive control. Treated rats were bred to two virgin females each week for 7-8 weeks. The females were killed in the 3rd week of gestation, and their uteri were examined for corpora lutea, early and late fetal deaths, and total implantations. Results were compared both to a negative control group bred to male rats that had received only the saline vehicle, to the positive controls, and to historical controls totaling about

WCD 001127

100 females. Although significant differences from control values, in some instances appearing to be dose related, were seen in some experimental groups during 1 or more weeks of breeding, these differences were not consistent and showed no overall dose relationship or time-trend patterns. Talc was therefore considered to be nonmutagenic in the dominant lethal assay system at the doses tested.

The teratogenic potential of talc in corn oil was evaluated for the FDA with screening tests on rabbits, mice, rats, and hamsters [78]. Dutch-belted rabbits received talc by intubation at 2.5-900 mg/kg/day on days 6-18 of gestation, and fetuses were examined following cesarean section on day 29. Albino CD-1 mice and Wistar rats were given talc in oral doses of 10-1,600 mg/kg/day on days 6-15 of gestation; mouse fetuses were examined on day 17 and rat fetuses on day 20. Golden hamsters recieved talc orally at 12-1,200 mg/kg/day on days 6-10 of gestation and fetuses were examined on day 14. As a positive control, rabbits were given 2.5 mg/kg of 6-aminonicotinamide on day 6 and other species received aspirin in daily doses of 150 or 250 mg/kg. The animals were observed throughout gestation for changes in food consumption and weight. At the end of the gestation period, their uteri were examined for numbers of corpora lutea, implantation and resorption sites, and live or dead fetuses. Fetuses were weighed, and live rabbit fetuses were incubated for 24 hours to determine survival. For all species, fetuses were examined for external and visceral abnormalities and were cleared for determination of skeletal abnormalities.

In all four species, talc at the doses tested had no effect on

WCD 001128

implantation or maternal or fetal survival [79]. The numbers and types of fetal abnormalities did not differ from those occurring spontaneously in controls treated only with the corn oil vehicle. No studies showing reproductive effects from exposure to talc have been found.

Correlation of Exposure and Effect

Toxicologic information in the available literature on humans and animals exposed to talc dust does not adequately characterize talc according to its particle size, mineral composition and purity. The severity of the health effects observed in workers exposed to talc appears to increase in workers exposed to talc containing asbestiform minerals, such as tremolite and anthophyllite, or containing free silica, and in those workers exposed for more than 10 years.

Short-term exposure to unknown but large quantities of cosmetic talc (talcum powder) was found to produce respiratory distress and some deaths in infants [20, 25, 28, 29, 24, 30, 31]. Respiratory signs and symptoms such as labored breathing, wheezing, coughing, and expectoration have been reported in one person not occupationally exposed to talc but who dusted himself and his bed linen with large quantities of cosmetic talcum powder for a period of 24 years [23]. Persistent and productive cough has been reported in one case of a worker who sprayed 25-50 cans/hour of pure talcum powder aerosol, as part of her job, at unknown concentrations for 1 week out of 6 for a period of 6 years [21]. In addition to the respiratory symptoms, all these individuals developed pulmonary lesions and granulomas.

WCD 001129

Pulmonary fibrosis has also been reported in workers exposed to nonasbestiform talc with and without free silica. Two of 46 workers (4.3%) who developed pulmonary fibrosis had been exposed to nonasbestiform talc containing about 1.4% free silica, at concentrations of 171-199 (28.5-33.2 mg/cu m) for 23-26 years [58]. Three of 13 workers (23%) exposed to nonasbestiform talc containing about 1.4% free silica, at average concentrations of 42.7 mppcf (10.5 mg/cu m) for 17.9 years, also developed pulmonary fibrosis [40].

Talcosis has been reported in five workers exposed for a period of 30 years to nonasbestiform talc containing less than 1% free silica at average concentrations of 37 and 50 mppcf (6.2 and 9.7 mg/cu m) [39]. A case control study [55] has shown that workers exposed to nonasbestiform talc containing less than 1% free silica at average concentrations less than 1 mg/cu m (6 mppcf) for 8.9 years developed increased incidences of respiratory symptoms when compared with those of controls. Of the 22 workers who were nonsmokers, there was increased incidences of cough (4.5%) and excess phlegm (12.3%) compared with increased incidences of cough (15.8%), excess phlegm (21%), wheezing (15.8%) and chronic obstructive lung disease (12.5%) in 56 workers who smoked. The increases in the respiratory symptoms were found to be statistically significant for smokers but not for nonsmokers and their controls.

A study [20] of 72 workers exposed to nonasbestiform talc with no free silica revealed x-ray film abnormalities after exposure to talc, and after 6-7 years of exposure, more than 25% of the workers showed abnormal

WCD 001130

roentgenographic pictures. A group of 392 workers exposed at various
unspecified levels of nonasbestiform talc not containing significant free
silica were found to have an increased risk of death from nonmalignant
respiratory disease, most of them with roentgenographic readings consistent
with pneumoconiosis [52].

A significant decrease in FEV 1 was reported in workers who smoked and were exposed to nonasbestiform talc at concentrations of 0.5-3.55 mg/cu m for about 5.9 years [55]. Another study showed a decrease in FEV 1 (87.6%) in workers who smoked for an average of 18 years and were exposed to nonasbestiform talc at 1.91 mg/cu m for 20 or more years [57].

Information from animal experiments indicates that talc produces similar effects on mammalian species tested. Pronounced respiratory changes such as inflammation in the larynx, trachea, and bronchi were observed in rats exposed to cosmetic talc at an average concentration of approximately 200 mg/cu m for 6 hours/day, 5 days/week, for 9 months [69]. In addition, the rats developed a fibrocellular reaction that produced focal fibrosis and emphysema in the lungs and a granulomatous reaction in the lymph nodes after 3-9 months. Bronchitis and fibrosis were reported in guinea pigs after 1-2 years of exposure at a total intratracheal dose of 150 mg [67].

Granulomas have been reported in patients exposed to cosmetic talc during surgical procedures [44,45]. One study reported a case of women who developed skin granulomas after applying talcum powder daily to open wounds [45]. Animal data have also shown granulomas in rats [70,46,71], rabbits [71,69], guinea pigs [71,69], and mice [70,71] after ip or laparotomic administration

WCD 001131

of talc.

Asbestiform talc has been shown to produce increased incidence of respiratory diseases in workers exposed for more than 10 years.

Pulmonary fibrosis has been reported in workers exposed to asbestiform talc, with and without free silica. Marked fibrosis was diagnosed in 6/8 workers (74%) exposed for 30 or more years, in 26/91 (29%) exposed for 10-30 years, and in 0/14 (0%) exposed for <10 years, to asbestiform talc containing 1% or less free silica at average concentrations of 6-5,000 mppcf (1-833.3 mg/cu m) (34). Fibrosis has also been reported in 19/156 workers (12%) exposed to asbestiform talc containing about 5% free silica, at concentrations of 69-1,227 mppcf for an average of 13 years (58), and six cases of diffuse fibrosis have been reported in workers exposed to asbestiform talc containing about 5% free silica, at an average concentration of 957 mppcf (26.2 mg/cu m) for an average of 24 years (37). Pulmonary fibrosis evidenced by roentgenographic observations has also been reported in 16 workers exposed to asbestiform talc containing less than 5% free silica, at an average concentration of 88.9 mppcf (11.5 mg/cu m) for 13-26 years (30), and in 42% of 30 workers exposed to asbestiform talc at concentrations of 65.1 mppcf (10.5 mg/cu m) for an average of 19.5 years (40). Of these latter workers, 50% were smokers.

Three studies (27,28,39) have reported cases of talcosis in workers exposed for more than 10 years to asbestiform talc containing less than 5% free silica at average concentrations exceeding 50 mppcf (8.3 mg/cu m).

Pulmonary function measurements such as vital capacity were reported

WCD 001132

significantly low (P<0.05) in 39 workers exposed to asbestiform talc (23.4%)
and in 87 workers exposed to nonasbestiform talc (13.8%) [40]. Decreases in
FEV 1, FVC, maximum ventilatory capacity, vital capacity, respiratory minute
volume, total lung volume, or diffusion capacity have been reported in workers
exposed for 10 years or longer at average concentrations greater than 50 mppcf
(6.3 mg/cu m) [36,37,38,39].

Symptoms of respiratory distress were reported by seventeen of 18 workers
who had been exposed to asbestiform talc containing 1% or less free silica, at
concentrations of 5-6,000 mppcf (1-833.3 mg/cu m) for 10 years or more [34].
The duration of exposure for one worker was not reported. Thirteen of these
workers complained of one or more respiratory symptoms including labored
breathing (10), chronic cough (7), chest pain (3), and excessive fatigue (5).
An increased prevalence of phlegm and cough has been found in 89 workers
exposed to asbestiform talc for >15 years [59]. In addition to these clinical
symptoms, diffuse rales and clubbing of the fingers were reported in six
workers exposed at average concentrations of 157 mppcf (26.2 mg/cu m) for an
average of 24 years [37]. Of 26 workers exposed to asbestiform talc at
average concentrations of 63.1 mppcf (10.5 mg/cu m) for an average of 19.5
years, 53% reported labored breathing and 27% had abnormal auscultatory sounds
such as rales, rhonchi, and wheezing [40]. Clinical symptoms and signs
reported for 43 workers exposed for an average of 19 years to asbestiform talc
containing 5% free silica at an average concentration of 62.3 mppcf (10.4
mg/cu m) included labored breathing (66.1%), cough (32.6%), lung crepitations
(27.9%), and clubbing of the fingers (18.6%) [58]. None of the 41 controls

WCD 001133

had coughing and clubbing of fingers; however, 4.9% developed labored
3217 breathing and lung crepitation. A comparison of 121 miners exposed to
3218 asbestiform talc containing up to 2.6% free silica with 9,347 coal and 1,995
3219 potash miners found pulmonary function measurements such as FEV1 and FVC to be
3220 lower and clinical signs and symptoms of respiratory disease to be more common
3221 [59].

3223 Asbestiform talc has been shown to produce massive exuberant macrophage
3223 and fibroplastic cellular proliferation, bronchiectasis and bronchitis with
3225 minimal fibrosis in six guinea pigs after 12 months at a single intratracheal
3226 dose of 75 mg [67]. As in humans, the severity of the fibrotic changes
3228 progressively increased with duration of exposure and with exposure to talc
3229 containing free silica or asbestiform minerals such as tremolite and
3230 anthophyllite [67].

3232 Talcosis has been diagnosed by respiratory symptoms such as productive
3233 cough, mucopurulent sputum, and labored breathing has been observed in eight
3234 workers after as few as 16 months after exposure at average concentrations
3235 greater than 11.5 mppcf (1.9 mg/cu m) to talc whose precise mineral
3236 composition was unknown but contained no free silica [41]. Talcosis diagnosed
3238 by roentgenographic examination was also reported in 16 of 50 workers (32%)
3239 exposed at average concentrations of 31-92 mppcf (5-15.3 mg/cu m) for 15 years
3241 [42].

3243 Exposure to nonasbestiform or asbestiform talc with or without free silica
3244 produces increased prevalences of cough, phlegm, and signs of respiratory
3245 impairment in humans. The prevalence of respiratory symptoms is greater in

WCD 001134

workers exposed to asbestiform talc than in those exposed to nonasbestiform talc. In addition, there appears to be an increase in the severity of respiratory impairment in smokers exposed to asbestiform or nonasbestiform talc.

Carcinogenicity, Mutagenicity, Teratogenicity, and Effects on Reproduction

Two epidemiologic studies have been reported on the carcinogenic potential of asbestiform talc in humans [64,391]. Data on 108 workers exposed for an average of 24 years to asbestiform talc containing various amounts of free silica at concentrations of 7-618 mppcf (4-126 mg/cu m) showed excess deaths from gastrointestinal (8), respiratory (13), and lung and pleural (12) cancer. More than a threefold increased incidence of deaths from respiratory cancer was observed in workers exposed to asbestiform talc for an average of 24 years. Although limited in nature, data from one animal study have shown that tremolitic talc was not carcinogenic in 50 hamsters after 700 days at a single intratracheal dose of 25 mg [761].

The incidence of death from respiratory and lung cancer in workers exposed to nonasbestiform talc containing 1-10% free silica, at concentrations of 2-35 mppcf (0.2-6 mg/cu m) was not significantly different [93]. Nonasbestiform talc was also found to have a low frequency of tumor induction in 36 rats, with only one rat developing a mesothelioma after 521 days [95].

Only two studies on the mutagenic and teratogenic effects of nonasbestiform talc have been reported in the literature. Mutagenic tests of nonasbestiform talc on microorganisms and animals showed nonmutagenic activity

WCD 001135

in host-mediated assay, cytogenic, and dominant lethal studies [77].

Teratogenic data from animals given varying doses of nonasbestiform talc during gestation showed no evidence of fetal abnormalities. At the doses tested, no effect was observed on implantation or maternal or on fetal survival [78]. No reproductive effects from exposure to talc have been found.

Summary of Tables of Exposure and Effect

The effects of exposure to nonasbestiform and asbestiform talc presented in Chapter III are summarized in Tables III-6, III-7, and III-8.

WCD 001136

TABLE III-6

SUMMARY OF EFFECTS ON HUMANS FROM EXPOSURE TO TALC

Talc Type and Composition	Air Exposure Concentration (mppcf)	Av Length of Exposure (yr)	Number of Workers	Respiratory Disease* (%)	X-ray Film Findings** (%)	Selected Pulmonary Function Measurements***	Reference
Tremolite, anthophyllite, serpentine, <5% free silica	62.3	19	43	65	37	20.3% decrease in vital capacity, 28.7% decrease in 1 sec vital capacity, 10% decrease in total lung capacity	(35)
Tremolite anthophyllite, <5% free silica	50	23.1	28	70	90	33.4% decrease in vital capacity, 33.5% decrease in 1 sec vital capacity, 41.2% decrease in maximum breathing capacity, 25.5% decrease in total lung capacity	(36)
Tremolite, anthophyllite, about 5% free silica	157	30	6	100****	100****	Reported for 1 patient only--35% decrease in vital capacity, 18.7% decrease in maximum breathing capacity, 10.4% decrease in total lung capacity	(37)
Tremolitic talc	57.1	19.5	30	53	43	21.4% decrease in vital capacity, 28.9% decrease in 1 sec vital capacity, 17.9% decrease in total lung capacity	(40)

WCD 001137

TABLE III-6 (CONTINUED)

SUMMARY OF EFFECTS ON HUMANS FROM EXPOSURE TO TALC

Talc Type and Composition	Av Exposure Concentration (mppcf)	Av Length of Exposure (yr)	Number of Workers	Respiratory Disease* (%)	X-ray Film Findings** (%)	Selected Pulmonary Function Measurements***	Reference
Nonasbestiform talc	62.7	13.9	13	46	23	13.2% decrease in vital capacity, 26.6% decrease in 1 sec vital capacity, 11.9% decrease in total lung capacity	[40]
Tremolitic talc, <1% free silica	5-5,000	>10	107	12*****	30#	No data	[34]
"	5-5,000	<10	221	No data	0#	"	[34]
Tremolitic talc, 5.1% free silica	<50	12.7	82	49	4	No data	[58]
"	>50	15	156	37	12	"	[58]
Tremolitic talc, 1.4% free silica	<50	10.3	15	40	0	"	[58]
"	>50	12.3	46	33	4	"	[58]
Tremolitic talc with anthophyllite, <5% free silica	66.9	21.4	16	88*****	100*****	27.5% decrease in vital capacity, 30.3% decrease in 1 sec vital capacity, 19.4% decrease in total lung capacity	[30]

WCD 001138

TABLE III-6 (CONTINUED)

SUMMARY OF EFFECTS ON HUMANS FROM EXPOSURE TO TALC

Talc Type and Composition	Av Exposure Concentration (mppcf)	Av Length of Exposure (yr)	Number of Workers	Respiratory Disease* (%)	X-ray Film Findings** (%)	Selected Pulmonary Function Measurements***	Reference
Granular talc, <1% quartz	37	25	2	100****	100****	No impairment of lung function observed, no measurements specified	[19]
"	58.5	20.2	3	100****	100****	"	[19]
Nonasbestiform talc (<2/cc), <1% free silica	<20	8.9	80	31%	0	1 sec vital capacity significantly lowered (P<0.01)	[55]
Nonasbestiform talc, no free silica	14-57%	2	8	100****	100****	56% decrease in average maximum breathing capacity, 44% decrease in average vital capacity	[41]
Unknown composition, no free silica	25-111	12	50	No data	32	Only 1 of 50 workers outside of normal range of pulmonary function measurements, measurements not specified	[42]

*Workers having at least one of the following: cough, phlegm, breathing difficulties, wheezing, clubbing of fingers

**Radiographic indicative of pneumoconiosis, fibrosis, abnormal shadows (author's opinion)

***Percentages derived from predicted pulmonary measurements

****Only workers diagnosed as having talcosis were examined

*****Subgroup of 18 workers reportedly exposed only to talc

#Slight or moderate fibrosis was not recorded.

Workers had rhelps for 3 mo.

WCD 001139

3447 #Some concentrations too high to measure

WCD 001140

WCD 001141

TALC FIRST DRAFT
TABLE III-7

EFFECTS ON ANIMALS EXPOSED TO TALC BY INHALATION

Talc Type	Species and Number	Concentration (mg/cu m)	Length of Exposure	Approx Cumulative Exposure (mg/cu m-hr)	Effects	Reference
Pharmaceutical*	Rats 7 M	23-383**	6 hr/d 5 d/wk 9 mo	350,000	Emphysema, pleural plaques, thickening of pulmonary arterial walls, granulomas	(65)
"	"	23-383**	6 hr/d 5 d/wk 6 mo	175,000	Thickening of pulmonary arterial walls, granulomas, severe inflammation	(65)
"	"	23-383**	6 hr/d 5 d/wk 3 mo	90,000	Mucous membrane inflammation, macrophage infiltration of alveolar lumina	(65)
"	"	23-383**	6 hr/d 5 d/wk 2 wk	17,000	Increased mucus in upper respiratory tract	(65)
"	"	23-383**	6 hr/d 5 d/wk 1 wk	8,500	No changes reported	(65)
Pharmaceutical**	Hamsters 48 M	8	2.5 hr/d 300 d	6,000	"	(66)
"	Hamsters 48 F	8	2.5 hr/d 300 d	6,000	Increased frequency of interstitial pneumonia and alveolar cell hyperplasia	(66)

TALC FINAL DRAFT

TABLE III-7 (CONTINUED)

EFFECTS ON ANIMALS EXPOSED TO TALC BY INHALATION

Talc Type	Species and Number	Concentration (mg/cu m)	Length of Exposure	Approx Cumulative Exposure (mg/cu m-hr)	Effects	Reference
*	Hamsters 49 M	8	0.5 hr/d 300 d	1,200	No changes reported	[66]
Pharmaceutical**	Hamsters 50 F	8	0.5 hr/d 300 d	1,200	Increased frequency of alveolar hyperplasia and alveolar histiocytosis	[66]
*	Hamsters 48 M	8	2.5 hr/d 30 d	600	No changes reported	[66]
*	Hamsters 50 F	8	2.5 hr/d 30 d	600	"	[66]
*	Hamsters 50 M	8	0.5 hr/d 30 d	120	"	[66]
*	Hamsters 49 F	8	0.5 hr/d 30 d	120	"	[66]
*	Hamsters 49 M	8	0.05 hr/d 30 d	12	"	[66]
*	Hamsters 47 F	8	0.05 hr/d 30 d	12	"	[66]

*Polish pharmaceutical talc of the type used in hospitals for preservation of surgical gloves and related uses

**Added in concentration of 200 mg/cu m

***High purity cosmetic talc powder sold in United States, over 95% (wt%) platy talc with trace quantities of carbonates, platy chlorite, and rutile.

WCD 001142

TABLE III-8

EFFECTS OF NONINHALATION EXPOSURE TO TALC AND TALC MIXTURES IN ANIMALS

Talc Composition	Route of Exposure	Species	Dosage	Effects	Reference
Talc dust, 3 fuln or less; 10% in water	Intratracheal injection	Guinea pigs	150 mg 3 doses	Inflammatory and foreign body reaction in lungs	[2]
Talc (50%) and tremolite (30%), 3 fuln or less; anthophyllite (20%), 20-50 fuln; 5% in water	"	"	75 mg 3 doses	Inflammatory and marked foreign body reaction in lungs	[67]
Talc (40%), tremolite (20%), and quartz (14%), 3 fuln or less; anthophyllite (17%), 20-50 fuln; 5% in water	"	"	75 mg 2 doses	"	[67]
Talc, 3 fuln or less, 1% in water	"	Rabbits	1 g 20 doses	Inflammatory and marked foreign body reaction in lungs and pleura	[67]

WCD 001143

TABLE III-8 (CONTINUED)

EFFECTS OF MINIMALATION EXPOSURE TO TALC AND TALC MIXTURES IN ANIMALS

Talc Composition	Route of Exposure	Species	Dosage	Effects	Reference
Talc, 3 fibs or less, 1% in water	Pleural injection	Rats	100 mg 10 doses	None	[67]
Pharmaceutical talc, 0.1% in saline	ip	Rabbits	10 ml 1 dose	Inflammatory and marked foreign body reaction in peritoneum	[69]
Pharmaceutical talc powder	ip laparotomy	"	Unknown	"	[69]
Pharmaceutical talc, 0.1% in saline	"	"	"	"	[69]
"	ip*	"	100 ml 1 dose	"	[69]
Pharmaceutical talc powder	"	"	Unknown	"	[69]
Pharmaceutical talc, 0.5% in saline	"	Guinea pigs	5 ml 1 dose	"	[69]
Pharmaceutical talc powder	ip	Guinea pigs, mice, rabbits	50 mg 1 dose	Adhesions and granulomas in peritoneum	[69]
"	Dermal*	"	10 mg 1 dose	"	[70]

*Skin cut or rubbed before talc was administered

WCD 001144

IV. ENVIRONMENTAL DATA AND ENGINEERING CONTROLS

Talc is a crystalline mineral that can become airborne when finely ground for commercial use. Sampling and analytical methods relate only to measurements of dust counts, fiber counts, mass concentrations, and the analysis of particle composition of the dust. The most commonly used methods are discussed below along with available information on workers' exposure and engineering control measures.

Dust Measurement

Dust count concentrations and total or respirable dust mass concentrations are the most common parameters used for evaluation of exposure to talc dust in workplaces. Many comprehensive reviews are available on this subject, although not all of these entirely deal with talc particles [80,81,82, 83,84,85,86,87,88]. The basic principles of the applicable methods are briefly discussed here.

(a) Counting Procedures

Microscopic counting of the number of dust particles collected by dry or wet impingement has long been used as an index to evaluate exposure to dust. Dry impaction devices, such as a Konimeter [89], Owen jet dust sampler [90], and Bausch and Lomb dust counter [91], were some of the earliest dust sampling devices developed in the 1920's and 1930's. They were widely used for coal dust sampling in South Africa and England. These

WCD 001145

devices used a piston pump to draw a single air sample of 5-50 ml through an orifice to create a high velocity jet for impaction of the particles on a glass slide or disc. A microscope is usually incorporated into the sampling device for direct counting of the particles collected. Collection efficiency is satisfactory down to the limit of resolution of the light microscope. However, interpretation of the results may be difficult because of the fracturing of particles caused by high velocity jet impaction.

In the 1940's, multistage jet impactors [91,92,93,94] were developed that collected larger volumes of air and separated the particles into different size-range groups. Air is drawn through a series of jets of decreasing width, which results in higher efficiencies of impaction for successively smaller particles. After calibration, particle size distribution can be determined by counting the particles deposited on each stage. One investigator [91] found that a four-stage impactor collected 1-5 micron particles of unit density with an efficiency approaching 100% at the last stage. The agglomerated particles are not shattered because they are collected in the initial stages at a relatively low impaction velocity. The aforementioned dry impingement methods can be used for sampling talc particles, but few tests were done for talc with these devices and no data were found. Even in general dust sampling, these devices are seldom used and a Bausch and Lomb Dust Counter is no longer commercially available [95].

Wet impingement is a more widely used method than dry impingement in

WCD 001146

the collection of dust particles. In an impinger, impingement takes place
3707 through a jet submerged in a liquid medium, usually water or alcohol.
3707 Greenburg and Smith [90] developed the original version of the impinger in
3709 1922. It operated at 1 cu ft/minute with 75 ml of liquid and developed an
3710 impingement velocity of close to 100 meters/second. A smaller midget
3710 impinger containing 10 ml of liquid and operating at 0.1 cu ft/minute with
3711 an impingement velocity of 70 meters/second was developed later [91].
3712 Details on efficiency and applications of both versions of impingers have
3713 been discussed by several investigators [88, 89, 35, 48]. Generally, the
3715 lower size limit of dust particle that could be counted by these methods
3717 depended on the sampling procedure and the resolution of the microscope.
3718 With a 10X-power objective lens, the controlling factor is the dust
3720 collector. For samples collected in impingers, the lower limit of
3721 detection is approximately 0.7 [ube [98].

3724 Because of different lower limits of counting resulting from different
3725 combinations of sampling and counting techniques, standardized methods were
3726 often used for interpretation of the results. A standard method for
3728 impinger sampling and dust counting was adopted in the United States in
3729 1942 [100] and was later revised [101]. With this latest method, air is
3730 collected in a midget impinger containing 10 ml of water at a flowrate of
3731 0.1 cu ft/minute, and the counting is done using a 10X-power objective
3732 lens. This dust-counting method accounted for all the particles collected
3733 in the liquid and that settled on the bottom of the counting cell at the
3734 time of counting. The resulting count was then a measure of overall dust

WCD 001147

concentrations rather than a specific measurement of a dust in question,
such as talc. Nevertheless, the dust count concentration was a useful
indicator of airborne particles in the workplace. The relative
effectiveness of control measures can also be evaluated using dust count
concentrations. Great improvements in the talc working environment have
been achieved judging from available data [58]. While this parameter might
be adequate in the pre-1950 days of dusty workplaces with high exposure
concentrations, efforts to further reduce the incidence of pneumoconiosis
and to define more clearly the relationship between biologic effects and
exposure have led to the development of a more refined dust measurement.

(b) Respirable Dust Measurement

Since pneumoconiosis is caused by excessive retention of dust in the
lungs, measurement of this portion of dust is a better parameter to
evaluate the respiratory health hazard. Dust particles that can be
deposited and retained in the lungs are generally referred to as respirable
dust. The British Medical Research Council defined it as the dust that
reaches the alveoli [102], while the US Atomic Energy Commission defined it
as that which penetrates to the nonciliated portion of the lungs [103].
Generally, particles with an aerodynamic equivalent diameter of 5-10 (um
or less of a unit density sphere are considered as respirable dust. To
determine mass concentration of such particles, a two-stage sampling device
is normally used with the first stage having the characteristics of dust
deposition in the upper respiratory tract and the second stage having those
of the pulmonary air spaces. Hatch and Newson [104] in 1948 suggested the

WCD 001148

use of a two-stage sampler, and several investigators have published custom
3766 specifications for such a device [100,100,102]. A list of two-stage
3769 respirable dust samplers that had been developed by various investigators
3771 was recently compiled by Lippmann [107]. Horizontal elutriators and
3772 cyclones have been the most widely used devices for the first stage, while
3773 the second stage generally uses a filter. A commonly used sampler is one
3773 that consists of a 10-mm nylon cyclone separator and a 37-mm diameter
3775 membrane filter.

3777 Total dust sampling has also been used for evaluation of workers'
3777 exposure to dust. Generally, a filter is used and the weight of the dust
3778 particles collected on the filter is determined to calculate mass
3779 concentration. This method is simple, but a few large particles collected
3780 could make up a disproportionately large part of the weight determined,
3782 obscuring a large number of smaller particles that present a greater health
3783 hazard.

3785 Therefore, NIOSH recommends sampling respirable dust to evaluate
3786 workers' exposure to talc. Samples should be taken at the employee's
3787 breathing zone over a full workshift to measure more closely the total
3789 exposure. The recommended method of dust collection is presented in
3789 Appendix I.

3792 Dust Analysis and Fiber Count

3795 Because talc deposits come from many different rocks and can exist in
3796 various metamorphic stages, there is hardly any ore that contains only pure

WCD 001149

talc [1068]. In fact, most of the talc ore mined contains only 45-60% pure
talc [1069]. The impurities are generally silicates or carbonates and are
in fibrous or nonfibrous form, but these do not usually interfere with the
intended uses of talc and are not removed from talc products. The question
then arises as to which component of talc product is more biologically
active. Kleinfeld [40] showed that talc containing fibrous minerals was
more hazardous to talc workers than that without fibers. Schepers and
Durkan [67] reported that the fibrous tremolite content of talc was the
main factor in causing diffuse pneumonitis in experimental animals. Quartz
contained in talc is also believed to cause a more severe response [19].
It is imperative, therefore, that to evaluate the health hazards of talc
dust exposure, the mineral composition and their morphology should also be
analyzed. Many techniques have been developed for this purpose, and most
of these have been reviewed or are being evaluated by NIOSH [1101].

In both the original [111] and the revised [112] NIOSH asbestos criteria documents, optical counting of fibers was recommended for the evaluation of worker exposure to asbestos. This method can also be adapted for evaluation of talc workers' exposure to asbestos. Air samples were collected on a membrane filter in an open-face filter holder. A portion of the filter was mounted on a slide and then rendered transparent for counting with phase contrast microscopy at 400-500X power magnification. Particles longer than 5 (um with a length-to-diameter ratio of 3:1 or greater were counted as fibers. Because of the limit of resolution of the light microscope and the imposed fiber definition, the resultant fiber

WCD 001150

count concentration is only a relative index of fiber exposure. Since not
3829 all talc contains asbestos fibers, this counting method would be used in
3831 those situations where it was either known or suspected that the talc
3832 contained asbestos fibers. However, since optical counting alone cannot
3833 identify the mineral species, the results may be misleading in cases where
3834 asbestos is but only one of the minerals encountered. For instance, Boundy
3835 et al [113] found that fibers in talc samples counted using phase contrast
3837 microscopy were often not asbestos fibers, as determined by scanning
3838 electron microscopy.

3840 For identifying fibrous minerals in a sample of talc, polarized light
3841 microscopy with a dispersion staining objective lens is often used [114].
3842 With this technique, the fibers are mounted in a dispersion liquid with a
3843 similar refractive index but a steeper dispersion curve than that of the
3844 fibers. A central stop is used in the back focal plane of the objective
3845 lens to allow for complementary color to appear around the particle
3846 boundaries. Dispersion staining imparts characteristic colors to each
3847 asbestos fiber, facilitating the detection and identification processes.
3848 It was reported that fibers with a dimension of 0.2 x 3 (um or larger
3850 could be detected in a sample containing more than 0.01% of fibers by
3851 weight. This technique is obviously limited by the resolution of the light
3852 microscope, which is about 0.2 (um. Because of this and possible
3853 interference from other minerals, optical microscopy is useful only as a
3854 preliminary analysis. Also, whether the existing sample counting technique
3855 can be applied to air samples is unknown.

WCD 001151

Transmission electron microscopy, with a magnification power of 1,500-40,000X, can examine all particles visually. By comparing morphologic characteristics, such as length-to-width ratio, diffraction contrast figures, cleavage characteristics, and edge characteristics, various fibers in a talc sample can be identified. Langer et al [115] reported that asphiboles (tremolite and anthophyllite) and chrysotiles can be easily distinguished by this technique, but asphiboles may be difficult to distinguish from talc fibers.

X-ray diffractometry is a standard mineralogic techniques used in the analysis of solid crystalline phases and has been widely used for analysis of talc samples. Because of characteristic diffraction of X-ray beams by talc and its associated mineral crystals, qualitative determination of the components of talc samples can be made. Quantitative analysis for each component can be done by comparing the intensities of appropriate diffraction peaks with those of calibrated standards. A number of excellent books and reviews [116,117,118,119,120] have discussed X-ray diffractometry in detail. Each mineral generally has its own distinct diffraction spectrum because of its crystalline structure. Quantitatively, a standard needs to be prepared for calibration. In a review of current technique for analysis of fibers in talc, Langer et al [121] pointed out the critical phase of selecting a mineral standard of high purity, proper sample preparation and dilution of the standard matrix.

X-ray diffraction analysis for quartz has been discussed in the NIOSH crystalline silica criteria document [122]. In this method, respirable dust

WCD 001152

is collected on a low ashing polyvinyl chloride filter and then redeposited
3890 on a silver membrane filter that is subject to X-ray diffraction analysis.
3891 Fluorite is used as an internal standard, and the intensity of diffraction
3892 peaks for quartz, cristobalite and tridymite are determined to calculate
3893 the percentage of free silica in the sample. As low as 5 ug of each free
3895 silica polymorph in a sample can be determined with this method.
3897 Using X-ray diffraction to determine asbestos content in talc samples,
3898 Mossadic and Crable [123,124] detected 1-5 ng for talc and 1-6 ng for
3899 tremolite in samples collected on a membrane filter and analyzed with
3901 external standard procedures. For bulk powder samples, internal standard
3902 procedures permit accurate analysis of a sample containing 15% or more of
3903 talc or tremolite by weight. Using the step-scanning mode of operation,
3904 Kohl and Langer [125] were able to detect anthophyllite at a concentration
3905 of 2%, chrysotile at 0.25%, and tremolite at 0.1% by weight in a binary
3906 matrix with talc. Schelz [126], using the same procedures, was able to
3907 detect amphiboles at <0.5% by weight in a talc matrix. Since X-ray
3909 diffractometry reveals only the crystalline structure of a mineral, the
3910 shapes of the particles cannot be determined. Thus, whether or not the
3911 tremolite or anthophyllite identified exists in fibrous form cannot be
3912 determined. There is no problem for chrysotile, since it exists only in a
3913 fibrous form. Birks et al [127] studied the quantitative analysis of
3915 airborne asbestos using X-ray diffraction. A specially designed apparatus
3916 containing two X-ray detectors was used, and the fibers were aligned in an
3917 electrostatic field to enhance diffraction intensity. A detection limit of

WCD 001153

0.4-0.5 fg/g for chrysotile was reported, but the technique has not been applied to actual environmental samples.

The method recommended by the Cosmetic, Toiletry, and Fragrance Association uses a combination of X-ray diffractometry, dispersion staining techniques, and morphologic characterization to confirm the presence of fibrous amphiboles in talcum powder through successive elimination processes [12d]. First, X-ray diffractometry determines the presence of amphiboles, then the dispersion staining procedure identifies those fibrous amphiboles conforming to certain morphologic parameters. To minimize interferences from carbonates in the sample during dispersion staining, the sample is first leached with hydrochloric acid. This succession of analytical procedures permits a quick and positive identification of fibrous amphiboles in a powder sample. Of course, it cannot differentiate between the amphibole species. This technique is only applicable for qualitative analysis, and procedures remain to be developed for analyzing air samples quantitatively.

Differential thermal analysis is another technique that can be used to analyze asbestos in a mineral sample [126]. This technique is based on the characteristic endothermic or exothermic reactions caused by dehydration or formation of new phases when the crystals are heated. Thermograms of talc and chrysotile have peaks at different temperatures, but amphibole asbestos has peaks indistinguishable from that of talc. Therefore, chrysotile in a talc sample can be analyzed by this method. The minimum detection limit of this method is 1% chrysotile in mixture.

WCD 001154

A more advanced technique that can be used in the analysis of fibrous minerals is that of transmission electron microscopy with selected area electron diffraction [129]. This is based on a principle similar to X-ray diffraction, except that an electron beam from a transmission electron microscope is used, and only a small area of the sample is analyzed at one time. Thus, single fibers are examined, and the interplanar spacing dimensions and planar angular relationships are determined from diffraction patterns to differentiate chrysotiles from amphiboles. However, the particular species within the amphibole group still cannot be identified. A goniometer is often required to reorient the fiber into a favorable axis for analysis. The higher the energy in the electron beam, the thicker the fiber that can be analyzed; however, thin fibers may not generate enough interferences to produce a diffraction pattern.

For a definitive analysis of the fibers in a talc sample, electron beam microchemical analysis in combination with transmission or scanning electron microscopy is sometimes used. The electron beam microchemical analysis is based on the concept that X-rays characteristic of the element present in a specimen are produced when it is bombarded with high energy electrons. Two probe techniques, wavelength dispersive and energy dispersive X-ray analysis, are used. The latter is more commonly used because it requires less time for an analysis [129]. All elements with an atomic number greater than 10 can be analyzed with this probe technique. Thus, chemical composition of a fiber or particle is determined. Coupled with the morphologic information derived from scanning microscopy or

selected area electron diffractometry, a fiber can be specifically identified as to its mineral species. The use of an electron microscope cells for special preparation of the sample. Zumwalde and Dement [1980] have described such a procedure. Briefly, the air sample collected on a membrane filter is transferred to an electron microscope grid after the sample is fused with acetone and coated with carbon. The electron microscopy and X-ray analysis technique is quite time consuming and requires rather expensive equipment and special training, but it is the only one that will generate definitive results.

There is no simple and satisfactory method for analysis of a talc sample collected either from workroom air or from bulk powders. Some methods such as X-ray diffraction or selected area electron diffraction identify only the mineral content but not the shape of the particles. Other methods such as optical microscopy and transmission electron microscopy will reveal the shape of a particle but not the nature of its mineral content. Combination of some of the methods, such as the one suggested by the Cosmetic, Toiletry, and Fragrance Association is only suitable for qualitative identification. Only the combined technique of energy-dispersive X-ray analysis coupled with transmission or scanning electron microscopy can perform qualitative and quantitative analysis at the same time. Therefore, NIOSH recommends this technique for analysis of talc dust samples and the airborne asbestos fibers that may be contained in the samples. Air samples should be collected on an open-face membrane filter. Fiber concentration can be determined from the number of fibers positively identified within a randomly selected number of grid openings.

WCD 001156

For statistical accuracy, a minimum of 10 field openings or 50 fibers should be examined for each sample (110). Details of this technique are presented in Appendix II.

In view of the complex mineral composition of talc dust, NIOSH recommends that respirable dust samples and fiber count samples (open face filter) be taken simultaneously. The respirable dust sample should also be analyzed for its free silica content.

Environmental Concentrations

There have been many reports in the past 30-40 years on talc pneumoconiosis. Most of these investigations have reported exposure concentrations in addition to observed or measured physiologic changes in workers who had worked in talc mines, mills, and related plants. Therefore, it is possible from these reports to document the changes and results of engineering controls that were undertaken to reduce workers' exposure to talc.

Dreesen (32), in 1933, reported that in a mining and milling plant, jackhammer drillers were exposed to tremolitic talc at an average concentration of 1,440 mppcf (240 mc/cu m), and millers were exposed at about 52 mppcf (8.7 mc/cu m). Sixty-eight percent of these talc particles were found to be <2 (um in diameter. Dreesen and DallaValle (33) investigated two Georgia mines and mills in 1935 and found that drillers in the mines were exposed at 455 mppcf (142.5 mc/cu m) and muckers at 32 mppcf (5.3 mc/cu m). In the milling plants, the packermen had the highest

WCD 001157

exposure at 1,072 mppcf (278.7 mg/cu m), followed by sawyers (blockers, stainers, and pencilmen) at 324 mppcf (54 mc/cu m).

The Division of Industrial Hygiene of the New York State Labor Department has conducted extensive surveys of talc mines and mills within the state since the 1930's, and thus, the data offered one of the best examples of improvements in the work environment. The first study was reported by Siegal and associates [34,130] in 1943 on plants located in St. Lawrence County. Midget impingers were used to collect air samples, and average concentrations of 1,350 mppcf (225 mc/cu m) for drilling, 1,290 mppcf (215 mg/cu m) for stoping, and 35 mppcf (5.8 mg/cu m) for mucking were found in the mines. In the milling plants, workers who performed bagging were exposed at 163 mppcf (27.2 mc/cu m), those involved in manual hauling were exposed at 215 mppcf (35.8 mg/cu m), and exposures at other operations were in the range of 46-93 mppcf (7.7-15.5 mg/cu m). A follow-up study reported by Kleinfeld [35] in 1955 found a dramatic improvement in the workplace environment. In the mines, average concentrations were only 3 mppcf (0.5 mg/cu m) for drilling, 4 mppcf (0.6 mc/cu m) for mucking, and 11-37 mppcf (1.8-6.2 mg/cu m) for various operations in the milling plants. These improvements were brought about by a number of changes including wet drilling, mine ventilation, enclosure of the elevators and chutes, installation of automatic bagging machines, conveyorized car loading, discontinuance of the blow room, and provision of local exhaust ventilation. Changes of similar magnitude were also seen in mines and milling plants in Lewis County in New York during the same time period

WCD 001158

[58]. The data as reported by the authors are presented in Table IV-1. It should be pointed out that the pre-1940 data as reported by Kleinfeld et al [35] were different than those reported by Siegel et al [34,139]. The latter reports included more data but reported only the average values.

WCD 001159

TABLE IV-1

COMPARISON OF DUST CONCENTRATIONS IN TALC PLANTS IN NEW YORK STATE

A. Plants in St. Lawrence County

	Old (up to 1945)				New (1946-1958)			
	Low	Med.	High	Av	Low	Med.	High	Av
Mines								
Drilling	83	413	2,600	818	0	2	8	3
Mucking	2	30	475	120	2.5	4	5	4
Mills		(Up to 1948)				(1948-1958)		
Crushing	22	69	690	180	3	13	360	32
Screening	43	68	136	69	8	35	88	37
Milling	32	75	271	92	5	15	60	20
Garners and Seperators	58	71	728	278	3	10	21	11
Bagging	26	129	520	151	5	17	90	24
Blow room	115	1,196	2,480	1,227	-	Discontinued		
Open chutes	21	83	640	125	-	Discontinued		-

WCD 001160

TALC FINAL DRAFT
TABLE IV-1 (CONTINUED)

COMPARISON OF DUST CONCENTRATIONS IN TALC PLANTS IN NEW YORK STATE

B. Plants in Lewis County

	Old (up to 1945)				New (1946-1958)			
	Low	Med.	High	Av	Low	Med.	High	Av
Mines								
Drilling	(No dust counts done)				0	-	2.5	1
Mucking	"				2.5	5	7.5	5
Mills								
Crushing	104	124	280	171	19	23	41	27
Screening	152	352	672	386	69	106	113	96
Milling	47	242	575	256	13	15	55	23
Separators	179	665	1,090	537	25	26	60	37
Bagging	80	197	320	199	19	66	113	66

Adapted from [58]

WCD 001161

After the engineering controls were instituted in 1965-1968, the trend of improvement of the work environment seemed to have reached a steady state as indicated in the data in Table IV-2, which were compiled by Kleinfeld et al [64] in 1974. This trend was expected since there had not been any major change in underground talc mining technology since wet drilling was introduced. It should also be pointed out that the frequency of the sampling, accuracy of the data, and representativeness of the samples were unknown.

WCD 001162

TALC FIRST DRAFT
TABLE IV-2

COMPARATIVE TALC DUST CONCENTRATION (In mppcf)
AT VARIOUS MINING AND MILLING OPERATIONS

	Pre 1945		1946-1965		1966-1969		1972	
	Av	Med.	Av	Med.	Av	Med.	Av	Med.
Drilling	810	413	5	3	19	19	7	7
Mucking	120	30	5	5	9	9	3	3
	Pre-1948		1948-1965					
Crushing	180	69	42	33	28	20	35	15
Screening	69	61	37	37	-	-	-	-
Milling	92	75	25	20	40	24	7	7
Garnering and Separating	216	70	27	27	-	-	13	9
Pulverizing	-	-	28	28	-	-	-	-
Bagging	151	129	27	23	29	25	27	27
RP and Truck Loading	-	-	73	63	43	20	36	20
Blow Room	1,227	1,196	-	-	-	-	-	-
Open Chutes	125	83	-	-	-	-	-	-

Adapted from 1941

WCD 001163

More recently, respirable dust concentrations have been used to determine worker exposure to talc. Houndy et al [1-3] used this sampling procedure to evaluate the work environment in three talc producing plants in Vermont in 1975 and 1976. The miners were found to be exposed at 0.4-2.0 mg/cu m (2.5-12 mppcf), with the driller, scraper, and muckers having higher exposures. The authors found that the laborers and maintenance personnel could also be exposed at high concentrations depending on their work assignments. In the open-pit and walk-in mines, the average concentrations at all operations were higher than in underground mines, with automatic mining machine operators exposed at 5.8 mg/cu m (34.8 mppcf) and drillers at 3.8 mg/cu m (22.8 mppcf). Average concentrations in the milling plants were found to be 0.9-2.9 mg/cu m (5.4 mppcf). The crushers, dry mill operators, baggers, and pelletizers were generally exposed at the upper concentration range.

NIOSH conducted an industrial hygiene survey of a mine and mill in New York State in 1975 in which respirable dust concentrations and total dust counts were two of the parameters measured. The TWA respirable dust concentrations ranged from 0.42 mg/cu m for the maintenance mechanic to 1.29 mg/cu m for the scrapper man. The corresponding dust count concentrations were 1.5 and 11.8 mppcf, respectively. The highest dust count found was 15.8 mppcf for the mucker; the respirable dust concentration was not determined. In the mill, the TWA respirable dust concentration ranged from 0.25 to 2.96 mg/cu m. The millwright and his helper were exposed at concentrations higher than 2 mg/cu m while the

WCD 001164

packerhouse workers were exposed at <0.5 mg/cu m. Only a few dust count concentrations in the mill were determined, which ranged from 0.5 to 3.6 mppcf.

As mentioned earlier, talc ore is always found with other minerals. Since such associated minerals as asbestiform fibers and free silica are major health concerns, their concentrations in workplace air have also been investigated. The NIOSH study [13] on a New York State talc operation mentioned above also determined asbestos fiber concentrations and free silica concentrations. The TWA fiber concentrations, determined by optical microscopy, were found to be 1.7-9.6 fibers >5 fu/cc. The crusher operator, trammer, and tarpman in the mine, and the foreman, laborer, crusher operator, handling operator, wheeler operator, and packer in the mill were exposed at higher than 5 fibers >5 fu/cc. Using electron microscopy, the TWA asbestos fiber concentrations (all lengths) were found to be 0.5-70.5 fibers/cc. The investigators also compiled previous data on fiber concentrations for this plant. This compilation is presented in Table IV-3. In the same study, analysis by electron microscopy also revealed that 38-49% of the airborne fibers were anthophyllite, 12-19% were tremolite, with the rest not identified. The free silica concentrations found in the same plant was very low, with the highest TWA concentration at 0.06 mg/cu m, which is lower than the permissible TWA concentration of 0.05 mg/cu m recommended by NIOSH [172]. The study by Boundy et al [113] on Vermont talc also analyzed samples for asbestos and quartz content. Using electron microscopy and step-scanning X-ray diffraction analysis, the

WCD 001165

investigators found no asbestos fibers in the samples. Fifteen percent of

4267 the bulk sample analyzed was found to have had trace amounts of quartz.

WCD 001166

TALC FIRST DRAFT
TABLE IV-3

SUMMARY OF HISTORIC FIBER EXPOSURE MEASUREMENTS AT A MINING AND MILLING PLANT IN NEW YORK*

Job or Operation	Mean Fiber Concentration (fiber >5 (u)m/cc)						
	1970	1972	1973	1974	1975	1975	1976
Mine							
Drilling	6	4	5	1	3	3	24
Dragline Loading	16	6	1	2	-	6	-
Tramming and Loading	23	8	1	-	3	6	6
Primary Crushing	200	22	5	9	20	10	25
Hoist Loading	39	5	10	13	3	10	12
Mill							
Secondary Crushing	13	5	14	6	9	5	18
Wheeler Grinding	30	-	14	12	17	8	14
Hardinge Grinding	33	-	-	13	10	8	14
Bagging	20	-	11	15	6	5	14
Palletizing	27	-	8	15	-	4	-
Bulk Loading	8	-	-	-	-	2	-
Loading Cars	-	-	-	-	-	3	-
Other							
Millwright	-	-	9	-	-	2	-
Maintenance	-	-	14	-	-	2-4	38

*Data calculated from MFSA reports, except where otherwise noted
Adopted from [131]

WCD 001167

More recently, respirable dust concentrations have been used to determine worker exposure to talc. Bounds et al [113] used this sampling procedure to evaluate the work environment in three talc producing plants in Vermont in 1975 and 1976. The miners were found to be exposed at 0.4-2.0 mg/cu m (2.5-12 mppcf), with the driller, scraper, and muckers having higher exposures. The authors found that the laborers and maintenance personnel could also be exposed at high concentrations depending on their work assignments. In the open-pit and walk-in mines, the average concentrations at all operations were higher than in underground mines, with automatic mining machine operators exposed at 5.8 mg/cu m (34.8 mppcf) and drillers at 3.8 mg/cu m (22.8 mppcf). Average concentrations in the milling plants were found to be 0.9-2.9 mg/cu m (5.4 mppcf). The crushers, dry mill operators, bagers, and palletizers were generally exposed at the upper concentration range.

NIOSH conducted an industrial hygiene survey of a mine and mill in New York State in 1975 in which respirable dust concentrations and total dust counts were two of the parameters measured. The TWA respirable dust concentrations ranged from 0.42 mg/cu m for the maintenance mechanic to 1.29 mg/cu m for the scrapper man. The corresponding dust count concentrations were 1.5 and 13.8 mppcf, respectively. The highest dust count found was 15.8 mppcf for the muckers the respirable dust concentration was not determined. In the mill, the TWA respirable dust concentration ranged from 0.25 to 2.96 mg/cu m. The millwright and his helper were exposed at concentrations higher than 2 mg/cu m while the

WCD 001168

packerhouse workers were exposed at <0.5 mg/cu m. Only a few dust count concentrations in the mill were determined, which ranged from 0.5 to 3.6 mppcf.

As mentioned earlier, talc ore is always found with other minerals. Since such associated minerals as asbestiform fibers and free silica are major health concerns, their concentrations in workplace air have also been investigated. The NIOSH study [131] on a New York State talc operation mentioned above also determined asbestos fiber concentrations and free silica concentrations. The TWA fiber concentrations, determined by optical microscopy, were found to be 1.7-9.8 fibers >5 (um/cc. The crusher operator, trammer, and tramman in the mine, and the foreman, laborer, crusher operator, handling operator, wheeler operator, and packer in the mill were exposed at higher than 5 fibers >5 (um/cc. Using electron microscopy, the TWA asbestos fiber concentrations (all lengths) were found to be 9.5-73.6 fibers/cc. The investigators also compiled previous data on fiber concentrations for this plant. This compilation is presented in Table IV-3. In the same study, analysis by electron microscopy also revealed that 30-69% of the airborne fibers were anthophyllite, 12-19% were tremolite, with the rest not identified. The free silica concentrations found in the same plant was very low, with the highest TWA concentration at 0.04 mg/cu m, which is lower than the permissible TWA concentration of 0.05 mg/cu m recommended by NIOSH [172]. The study by Boundy et al [113] on Vermont talc also analyzed samples for asbestos and quartz content. Using electron microscopy and step-scanning X-ray diffraction analysis, the

WCD 001169

investigators found no asbestos fibers in the samples. Fifteen percent of

4207 the bulk sample analyzed was found to have had trace amounts of quartz.

WCD 001170

TALC FIRST DRAFT
TABLE IV-1

SUMMARY OF HISTORIC FIBER EXPOSURE MEASUREMENTS AT A MINING AND MILLING PLANT IN NEW YORK*

Job or Operation	Mean Fiber Concentration (fiber >5 (u)m/cc)						
						NIOSH	
	1970	1972	1973	1974	1975	1975	1976
Mine							
Drilling	8	4	1	1	1	3	24
Dragline Loading	16	6	1	2	-	6	-
Tramming and Loading	22	6	1	-	3	6	8
Primary Crushing	260	22	5	9	20	10	25
Hoist Loading	39	5	10	13	5	10	12
Mill							
Secondary Crushing	13	5	14	6	9	5	18
Rhumler Grinding	30	-	14	13	17	8	14
Hardinge Grinding	33	-	-	11	10	8	14
Bagging	30	-	11	15	6	5	14
Pelletizing	27	-	8	15	-	4	-
Bulk Loading	8	-	-	-	-	2	-
Loader Back	-	-	-	-	-	3	-
Other							
Millwright	-	-	9	-	-	2	-
Maintenance	-	-	14	-	-	2-4	38

*Data calculated from MESA reports, except where otherwise noted
Adapted from [13]

WCD 001171

Exposure to talc dust do not limit to the miners and millers only. workers engage in work that use talc in the process are also exposed to talc dust. In 1972, NIOSH [131] conducted a talc dust industrial hygiene survey on a rubber band production facility. Because talc was being used in a careless manner and in an amount in excess of that need for lubrication and because of poor ventilation and housekeeping, rather high dust concentrations were found. The respirable dust concentrations were 2.5-7.8 mg/cu m (average 4.8 mg/cu m) for the extruders, 5.3 and 6.1 mg/cu m for two vulcanizers, and 0.9 and 1.3 mg/cu m for two cutters. The average total dust concentration ranged from 5.4 mg/cu m for the duster in the mixing building to 141.4 mg/cu m for the vulcanizers. In addition, fiber concentrations as determined with phase contrast optical microscope ranged from 4.9 to 19.2 fibers >5 (um/cc, except 1 fiber/cc for the packer. Analysis of the airborne dust also revealed that the dust contained 2-3% free silica. Subsequently, the plant substituted some of the talc with antistick plastic sheets and used only a minimum amount of talc, improved the existing ventilation and added new systems, and used a vacuum cleaner for floor cleaning to improve work environment. A resurvey [133] consisting of a walk-through inspection and collection of four personal samples in 1973 proved that the modification was effective. The respirable dust concentrations found then were 2.2 mg/cu m for the extruder with the new ventilation system, 4.2 mg/cu m with the improved ventilation system, 1.7 mg/cu m for the packer (in the same room as vulcanizers), and 3.0 mg/cu m for the laborer operating the vacuum cleaner.

WCD 001172

4341 Engineering Controls

4344 During the early 1950's, a substantial reduction in dust concentrations
4345 in mining and milling operations was reported, marking a great improvement
4346 in engineering techniques used in these processes.

4348 In mines, high dust concentrations occurred during dry drilling,
4349 blasting, and mucking operations [34,130]. However, after wet drilling
4349 techniques were instituted in mining operations, airborne dust
4350 concentrations were markedly reduced [35]. Similarly, a marked reduction
4351 in dust levels was reported in mills after installing engineering controls
4352 such as enclosure of elevators and chutes, installation of automatic
4354 bagging machines, conveyorized car loading, discontinuance of blowrooms,
4356 and local exhaust ventilation.

4357 Local exhaust ventilation can also be effectively used to control dust
4358 levels in operations such as the manufacture of ceramics, paint, paper,
4359 roofing, and other materials that extensively use talc or talc-containing
4360 materials. Information on ventilation design and control procedures can be
4361 found in Industrial Ventilation....A Manual of Recommended
4362 Practice, in Fundamentals Governing the Design and
4363 Operation of Local Exhaust Systems 2V.2-1971 and in NIOSH's
4364 Recommended Industrial Ventilation Guidelines.

WCD 001173

V. WORK PRACTICES

A high incidence of talc pneumoconiosis [58, 37, 34, 27, 35] and lung cancer [64, 63] had been reported in talc workers prior to institution of wet drilling techniques in the mines and effective process enclosure and exhaust ventilation systems in the mills and end user plants. Dust levels in these plants frequently far exceeded 20 mppcf, the current Federal limit for nonfibrous talc. Presently, because of effective engineering controls installed in most talc workplaces and education of employees of proper procedures for handling of talc and good work practices, employee exposure to high talc dust levels has been minimized.

Workers' exposure to talc may occur in three places: in the mines, in the milling plants, and in end-user facilities. The nature of exposure varies according to where the exposure occurs. In the mines, dust particles are generally coarser than in the other two places. In the milling plants, dust particles may range from very coarse to respirable size depending on the point of emission in the process. At the end-user facilities, only fine particles are expected. In addition to these apparent differences in exposure, work procedures are also different; therefore, in protecting workers from overexposure to talc, different work practices may be required to cope with the different situations.

In the mining process, the employer should adhere to the safety and mining procedures and regulations as required by MSHA. Briefly, mining

WCD 001174

personnel in processes such as wet drilling, blasting, machine mucking and
4403 stoping should be required to have proper protective clothing and
4404 equipment, since process enclosure is impossible. In certain operations
4405 such as automatic mining machine, an atmosphere-controlled cabin may be
4406 provided for the operators.
4409 In the milling plants, crushing, grinding, drying, classifying,
4409 bagging, and stacking are generally involved. A typical process flow
4410 diagram is shown below:

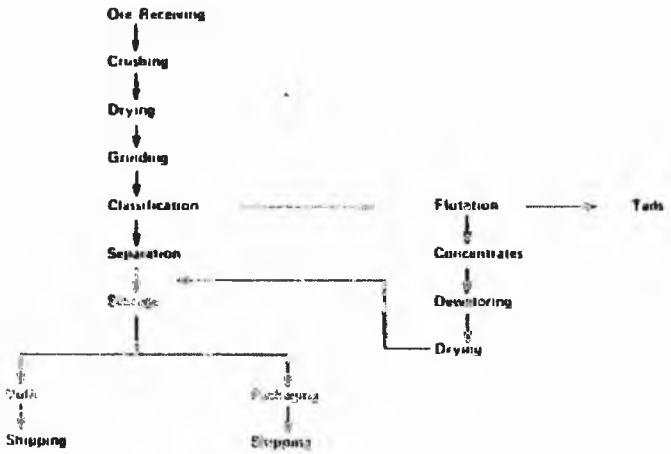


Figure V-1 TYPICAL MILLING FLOW DIAGRAM

WCD 001175

It has been observed that most of the process equipment involved in milling plants is totally enclosed and operated under negative pressure [109]. Thus, talc dust may be dispersed into the workplace at transfer points and from openings or cracks resulting from failure of the process equipment. It is important, then, that all process equipment be maintained in proper working order and checked routinely for defects. If defects are found, properly protected personnel (with protective clothing and respiratory equipment) should promptly repair the equipment. Any spill resulting from equipment failure or rupture of bags should be promptly removed to prevent it from being dispersed into the workroom air.

Because of its diverse physical properties, talc has various industrial applications [7]. For example, cosmetic grade talc is used for the production of talcum baby powder and as tablet filler in pharmaceutical products, and the industrial grade talc is used in paint, ceramics, paper, and rubber as filler, inert ingredients, or surfacing agents. Depending on the amount and the manner in which talc is used in a particular process, the exposure concentrations may vary several orders of magnitude [109]. Engineering controls such as process enclosure and exhaust ventilation should be used to control talc concentrations in workroom air. Protective clothing and respirators should be used in cleanup operations, maintenance, repair, or emergency situations.

As a fundamental objective in protecting employees' safety and health, the employer should maintain a clean workplace to minimize dust exposure. To prevent dust accumulation in the workplace, the floors and exteriors of

WCD 001176

process equipment should be frequently cleaned with a vacuum cleaning
4446 system. Local exhaust systems equipped with flexible ducts may be used to
4447 clean settled dust on the equipment. Although brooms and shovels have
4449 often been used for cleaning floors, vacuum cleaners are considered more
4450 effective because they disperse very little dust into the air. All
4451 personnel engaged in cleaning activities should be properly protected from
4452 dust exposure.

4454 Under normal operating conditions, respirators should not be used as a
4455 substitute for proper engineering controls. Respirators should be used
4456 only during emergencies, during maintenance activities, during cleaning of
4457 equipment, and when appropriate engineering controls or administrative
4458 measures are being installed or tested. Respirators conforming to Table 1-
4460 1 and approved under 30 CFR 11 should be provided to employees, and a
4461 respiratory protective program should be established in compliance with the
4462 current Federal standard, 29 CFR 1910.134. Emphasis should be directed
4463 toward providing clean, well-maintained, and fitted respirators for use in
4464 emergencies and unusual circumstances. The interior of the facepiece
4465 should not be contaminated with talc.

4467 To prevent excessive dust depositing on work clothes, especially during
4468 nonroutine operations, dust-resistant garments such as those with securable
4469 flaps over pockets or those with no folds should be worn over or used as
4470 the work clothes. For personal hygiene reasons, work clothes and street
4472 clothes should be kept in separate lockers. If compressed air is used to
4473 drive dust off the work cloth, it should be done only inside an exhaust

WCD 001177

hood and the workers involved should wear respirators. Shower and locker room facilities should be provided and the employees should be encouraged to shower before leaving the work area at the end of a shift. Because of possible synergism of cigarette smoking and talc in causing pulmonary diseases [95], smoking should be discouraged and the carrying of smoking or related materials i.e. snuff or chewing tobacco should be prohibited.

Protective clothing, respirator, and lifeline should be required for personnel entering confined spaces, such as vessels, ventilation ducts, and bachouses. Before entering, the process involved should be shut off and the space checked for oxygen deficiency and talc dust concentration. A second worker similarly equipped should watch at all times from outside the confined space. Two additional employees should be available to assist in the event of an emergency.

Employers should require new employees to participate in an orientation process in which they are informed of the adverse health effects that could result from long term exposure to talc at concentrations exceeding the recommended environmental limit. During this initial orientation, the employer should make certain that employees understand that talc is usually not encountered in a pure form and may be mixed with other minerals such as tremolite and anthophyllite, the fibrous forms of which are considered carcinogenic to human. Written information on the adverse health effects and signs and symptoms that can be caused by exposure to talc and associated minerals should be provided to employees. New information should be posted in areas accessible to employees.

WCD 001178

An ongoing education program should be established to allow an opportunity for employees to meet with management to review safety procedures and new toxicologic findings. Both the orientation and continuing education programs should be conducted by personnel qualified by experience or training in occupational safety and health.

WCD 001179

VI. DEVELOPMENT OF STANDARD

Basis for Previous Standards

In 1946, the American Conference of Governmental Industrial Hygienists (ACGIH) [134] at its eighth annual meeting established a maximum allowable concentration (MAC) for talc of 20 mppcf of air as determined by standard light field count [135]. The basis for this recommendation was not given. MAC's were redefined as threshold limit values (TLV's) in 1948 by the ACGIH and a TLV-TWA concentration of 20 mppcf was adopted for talc. The TLV for talc remained unchanged until 1962 when a stipulation was added that the 20 mppcf TLV applied only to those airborne talc dust containing <1% crystalline silica [136]. Any mineral dust with >1% silica content was to follow the new revised silica TLV. The Documentation of the Threshold Limit Values [137] published in 1962 indicated the basis for the talc TLV was a number of clinical studies, that associated talc exposures with pneumoconiosis [32, 33, 138, 130, 139, 140, 141, 142, 41, 143, 25, 61, 144, 145]. In most of these studies, it was recognized that the talc dust inhaled contained varying amounts of tremolite or other accessory minerals. However, Hague and Mallette [146] reported that workers exposed to pure talc dust at average concentrations of 15-50 mppcf for 10-30 years showed no evidence of pneumoconiosis. Schepers and Durkan [48] developed evidence on the complex interplay between talc, tremolite, and quartz from human studies, and evidence of many reported cases of talc

WCD 001180

pneumoconiosis resembling asbestosis. The ACGIH (1971 construed that the talc TLV applied to talc in the commercial sense that included a variety of products with similar physical characteristics regardless of actual talc content, not to the mineralogically pure form of talc. The recommended TLV was based largely on the work of Breesen and DallaValle (33), who reported on 66 workers handling Georgia talc containing 10% tremolite. They found no pneumoconiosis in workers who were exposed at average talc dust concentrations of 17 mppcf, whereas in workers exposed at average talc dust concentrations of 135 and 300 mppcf, severe and disabling cases of pneumoconiosis were found. The documentation also cited studies by Kleinfeld et al (35,59) on asbestiform talc workers to support the 20-mppcf TLV for exposure to talc dust.

The ACGIH in Threshold Limit Values for 1964 (147) added a TLV-TWA concentration for mixtures of mineral dusts to Appendix B. The general formula for mixtures was used to reflect that, when two or more biologically active mineral dusts are present, their combined effect, rather than that of either individually, should be given primary consideration for the TLV (147). The effects are considered as additive, and if the sum of the fractions exceeds unity, then the threshold limit of the mixture should be considered as being exceeded (147). Approximately the same result will be obtained when the most toxic component alone is considered for the TLV, provided the effects are additive (147).

In 1967, the ACGIH (148) noted tremolite as a hazardous mineral dust and established a TLV-TWA of 5 mppcf based on the asbestos TLV, since

WCD 001181

tremolite was considered as a form of asbestos [149]. This TLV and the talc TLV of 20 mppcf remained unchanged until 1970 [150] when the talc TLV referred only to nonasbestiform talc while the asbestos TLV of 5 mppcf would apply to asbestiform talc and tremolite since fibrous talc contained asbestos fibers. However, in 1968 [151] and 1969 [152] the ACGIH published notices of intended change to lower the asbestos TLV to 12 fibers >5 u/cc or 2 mppcf. The intended change for asbestos TLV was again revised in 1970 [153] to 5 fibers >5 (u)m/cc, a 15-minute ceiling limit of 10 fibers >5 (u)m/cc for no more than five times daily was proposed.

This intended change for the asbestos TLV, which covered asbestiform talc and tremolite, remained in effect until 1974 [154] when it was formerly adopted as a TLV.

According to the 1971 Documentation of Threshold Limit Values for Substances in Workroom Air [155], the ACGIH TLV for nonasbestiform talc of 20 mppcf was based largely on the work of Dreessen and DalleValle [33] as previously cited for talc in Documentation of Threshold Limit Values [117] for 1962. A dust count was recommended but if the content of the talc was variable or unknown, it was stated that it may be desirable to make both dust and fiber counts for nonasbestiform talc or material with a low fiber content.

The 1971 Documentation of Threshold Limit Values for Substances in Workroom Air [155], stated that the fibrous variety of talc and its associated amphiboles such as tremolite and anthophyllite, contain fibers that are classified as asbestos. Porro et al [138]

WCD 001182

investigated 15 cases of talcosis, including 5 autopsies, and reported asbestos bodies were almost always present in the fibrotic areas. They also noted a degree of similarity between asbestosis and talc pneumoconiosis. Siegal et al [130,34] reported on 221 asbestiform talc miners and millers and found an advanced fibrosis incidence rate of 14.5%. McLaughlin et al [136] indicated that talc pneumoconiosis could be caused only by the fibrous variety of talc, and that asbestos was considered to be more actively fibrogenic, possibly because of its higher number of fibers. In autopsies of eight talc workers, Schepers and Durkan [156] found microscopic indications that suggested that tremolite was the main pathogenic agent in the talc lung lesion. Kleinfeld et al [37] reported autopsy findings on six talc workers in which the bodies found in the respiratory bronchioles or in fibrous tissues were indistinguishable from asbestos bodies as seen in asbestosis. Thus the ACGIH [155], because of the similarity in the fibrotic reaction produced by talc and asbestos, recommended the asbestos TLV of 5 fibers/ml of air >5 (um in length for asbestiform talc.

In 1972, the ACGIH TLV Airborne Contaminants Committee [153] proposed that asbestos be listed as an occupational carcinogen with an assigned TLV and was adopted in 1974 [154]. The 1974 edition of the Documentation of the Threshold Limit Values [157] does not differ in substance or conclusion from the 1971 edition. The adopted TLV's [156] in 1973 for nonasbestiform talc, (20 mppcf), fibrous talc, and tremolite included the asbestos limit of 5 fibers/cc with fibers >5 (um in length. The Committee

WCD 001183

(1984), under "Appendix A, Carcinogens," noted that exposure to all forms of asbestos, together with cigarette smoking, can increase the incidence of bronchogenic carcinoma from asbestos and other substances or processes.

The present US General Standard (29 CFR 1910.1000 and 1910.1001) for workplace exposure to talc is an 8-hour TWA concentration of 20 mppcf for asbestiform talc containing less than 1% quartz. For asbestiform talc, the asbestos standard is used, which is an 8-hour TWA concentration of 2 fibers/cc for fibers >5 (um in length. In addition, the concentration of asbestiform talc is not to exceed 10 fibers/cc for fibers longer than 5 (um for any period of time (ie, a ceiling limit). The standard for nonasbestiform talc is based on the TLV for workplace exposure proposed by the ACGIH in 1970. The asbestiform talc standard is based largely on work done by the British Occupational Hygiene Society for a proposed standard for asbestos.

Basis for the Recommended Environmental Standard

(a) Permissible Exposure Limit

Most of the studies of the health effects of talc on workers found in the available literature do not adequately characterize talc by source, mineral composition, purity or particle size. Because talc is usually found in ores mixed with free silica and asbestiform minerals such as tremolite, anthophyllite and chrysotile, most human and animal studies involve exposure to mixtures of these substances. The environmental data are

WCD 001184

usually reported as total dust as determined by impinger methods in area
4686 samples, although a few epidemiologic studies report airborne dust
4687 measurements in the worker's breathing zone as respirable dust.
4688 A number of reports have revealed that exposure of workers to
4691 asbestiform and nonasbestiform talc with or without free silica at
4692 concentrations greater than 20 mppcf (3.3 mg/cu m) for 10 years or longer
4694 produced lung function impairment evidenced by decreases in vital capacity,
4695 respiratory minute volume, maximum ventilatory capacity, FVC, or FEV 1
4697 [36,37,38,39,40], talcosis characterized by labored breathing, coughing,
4698 and lung crepitation or by roentgenographic examination [36,58,37,39,40],
4700 and pulmonary fibrosis [58,37,39].
4702 Studies on workers exposed for 10 years or longer to asbestiform talc
4703 containing 5% or less free silica at average concentrations greater than 50
4704 mppcf (8.2 mg/cu m) showed pulmonary fibrosis [58,37,39], talcosis
4705 [37,38,39] and decreases in pulmonary function measurements [37,38,39,40].
4706 Talcosis was also reported in workers exposed, for 10 years or longer, to
4707 asbestiform talc containing 1% or less free silica at average
4708 concentrations greater than 50 mppcf (8.2 mg/cu m) [34]. Asbestiform talc
4709 containing various amounts of free silica caused excess deaths from
4711 gastrointestinal (8), respiratory (13), and lung (12) cancer in 108 workers
4713 exposed for an average of 26 years at average concentrations of 7-818 mppcf
4714 (1-136 mg/cu m) [64].
4716 Animals exposed at a single intratracheal dose of 75 mg of asbestiform
4717 talc produced fibrosis, bronchitis, and fibrocytic cellular proliferation

WCD 001185

after 12 months [67].

Workers exposed for 10 years or longer to nonasbestiform talc containing 1.4% or less free silica at average concentrations greater than 20 mppcf (3.3 mg/cu m) developed roentgenographic evidence of pulmonary fibrosis [58,40,57], talcosis [69], and decreases in pulmonary function measurements [40,57]. Nonasbestiform talc containing less than 1% free silica produced increased incidences of cough (4.5%), excess phlegm (21%), wheezing and chronic obstructive lung disease (12.5%) and decreases in FEV 1 in workers who were exposed at concentrations of 0.5-3.55 mg/cu m for 8.9 years [55]. Substantial decreases in FEV 1 (87.6%) were also reported in workers exposed to nonasbestiform talc at concentrations of about 1.91 mg/cu m for 22 or more years, and smoked for an average of 18 years. The risk of death from nonmalignant respiratory disease was also elevated in workers exposed for an average of 18 years to nonasbestiform talc containing no free silica [52].

Animals exposed to nonasbestiform talc at an average concentration of 200 mg/cu m or at a total intratracheal dose of 150 mg developed inflammation in the respiratory tract [67,65], fibrosis [67,65], emphysema in the lungs [65], and a granulomatous reaction in the lymph nodes [65] after 12 months.

All reviewed studies on the mutagenicity or teratogenicity of nonasbestiform talc demonstrated no mutagenic or teratogenic effects on species tested [77,78]. No information on carcinogenicity of nonasbestiform talc on animals was found.

4750 Data on human exposure to nonasbestiform talc have shown that
4751 nonasbestiform talc containing less than 1% free silica produces
4752 respiratory effects and progressive pulmonary function disturbances at
4753 concentrations as low as 0.5-3.5 mg/cu m respirable fraction after 8.9
4754 years of exposure in persons that smoke [55]. In view of the possible
4755 interaction between exposure to nonasbestiform talc and smoking and since
4756 it is not possible for NIOSH to regulate smoking in workers, NIOSH
4757 recommends that concentrations of airborne nonasbestiform talc be
4758 controlled at a level below that shown to produce adverse health effects in
4759 smokers. Because no adequate no-observable-effect exposure concentration
4760 has been demonstrated, it is NIOSH's professional judgement that the
4761 concentration of talc in the breathing zones of workers should be
4762 controlled so that no worker is exposed at concentrations greater than 0.1
4763 mg/cu m as determined by a previmetric method for respirable dust.

4766 Since silica contamination of talc is a possibility, and the available
4767 human data [55,91] and the animal data [67] indicate that talc with free
4768 silica may be more hazardous than talc without free silica. NIOSH also
4769 recommends that the silica content be determined by X-ray diffraction as
4770 stated in the NIOSH criteria document on crystalline silica. Talc found to
4772 contain crystalline free silica should comply with the environmental limit
4773 proposed for silica by NIOSH in this document.

4775 Since talc is often contaminated with asbestiform substances NIOSH also
4776 recommends that the environmental limit of these asbestiform substances be
4777 in accordance with the recommended limit for asbestos in the NIOSH revised

WCD 001187

criteria document on asbestos.

(b) Sampling and Analysis

The recommended method of sampling and analysis should be simple, sensitive, and specific for the mineral analyzed. In addition, sampling should be representative of the worker's breathing zone air without impeding normal job performance. As was discussed in Chapter IV, sampling on a two-stage sampler such as a combination of cyclone and filter is recommended for respirable dust measurement and for free silica analysis. Simultaneously, another sample should be collected on an open-face membrane filter for asbestos analysis using energy-dispersive X-ray analysis with transmission or scanning electron microscopy. Detailed information is given in Appendices I and II. The recommendation for dual sampling and triple analysis is necessitated by the diverse mineral contents of talc and its associated health hazards.

Respirable dust sampling is simple and straightforward and provides information closely related to hazards of talc particle inhalation. Analysis of free silica content by X-ray diffraction is a specific analysis for various forms of free silica and can detect as low as 5 fold in a sample. The method recommended for analysis of asbestos fibers is a rather complicated and expensive procedure, but it is the only method that can give quantitative information.

With the recommended sampling and analytical methods, a talc work environment can be evaluated as to the type of talc dust present, the mineral species, and their concentrations. Thus, whether the workers are

exposed to talc alone or to talc containing free silica or asbestos fibers
4813 can be determined.

4815 (c) Medical Surveillance and Recordkeeping

4818 A number of human and animal studies have demonstrated that exposure to
4819 nonasbestiform and asbestiform talc produced marked respiratory effects,
4821 pneumoconiosis, and pulmonary fibrosis. NIOSH, therefore, recommends that
4822 a medical surveillance program which includes preplacement and periodic
4823 medical examinations should be instituted for screening and monitoring of
4824 workers exposed to nonasbestiform talc. This surveillance program should
4825 establish a data base that includes information on smoking, medical and
4827 occupational histories, chest X-ray, pulmonary function tests including FVC
4828 and FEV 1, and an examination of the upper respiratory tract. Appropriate
4830 examinations of workers exposed to talc containing free silica or asbestos
4831 shall be performed as outlined in the respective NIOSH criteria documents
4833 on these two substances.

4835 Because pneumoconiosis and pulmonary fibrosis take a long time to
4836 develop and because retrogression of pulmonary fibrosis is slow, medical
4837 records should be maintained for at least 30 years beyond the duration of
4838 employment.

4840 (d) Personal Protective Equipment and Clothing

4843 Talc has not been found to be a dermal irritant; therefore, protective
4844 clothing is not necessary, however, work clothes should be provided for
4845 reasons of personal hygiene. To minimize the possibility of excessive dust
4847 exposure, respirators should be used in places where high dust

WCD 001189

concentrations may exist such as in bagging and packing areas because of
bag ruptures and during repair or nonroutine operations.

(e) Informing Employees of Hazards

Exposure to talc can cause talcosis or may even cause lung cancer because of the presence of asbestos fibers. Employees who may be occupationally exposed to talc should be advised of the adverse health effects from such exposure. Possible synergistic effect between talc exposure and cigarette smoking should also be stressed to employees. Information concerning the significance and methods of preventing or controlling exposure and of environmental and medical surveillance programs should be made available to the employees. These should be given to employee at the time of hiring and be reviewed periodically thereafter.

(f) Work Practices

Engineering controls such as process enclosure and local exhaust ventilation should be used to control dust concentration in workroom air. The process and control equipment should be routinely checked and maintained to ensure their effectiveness. Good work practices such as frequent housekeeping by vacuuming, prompt cleanup of spills, effective respiratory protection programs, proper waste disposal, good personal hygiene, and adequate training should be instituted to minimize employees' exposure to talc dust.

(g) Monitoring and Recordkeeping Requirements

To characterize the concentration of airborne talc dust in the employees' breathing zones, the employer should conduct periodic industrial

WCD 001190

hygiene surveys. Surveys should be conducted annually and within 30 days
of any process change likely to result in an increase in the concentrations
of airborne talc. If monitoring reveals that an employee is exposed above
the recommended environmental limit, the employee should be controls should
be initiated promptly notified, and the employee exposure should be
monitored weekly until two successive determinations at least 1 week apart
indicate that the environmental concentration is at or below the
recommended environmental limit. Records of workplace environmental
monitoring should be kept for at least 30 years after the employee(s) last
exposure to talc.

WCD 001191

VII. RESEARCH NEEDS

Animal Research

Although talc has been widely used in modern times in a variety of products that involve the exposure of a large number of people, basic research questions concerning talc have not been completely resolved. Among these is the pathogenicity of pure talc and the role of substances that commonly occur with talc. Asbestos [67,76] and free silica [67,68] contaminants have been widely researched, but other substances such as dolomite, chlorite, and brucite have not. Animal inhalation studies that definitely show the degree of pathogenic effects on pulmonary tissue of pure talc crystals, dolomite, chlorite, brucite, and the talc-related mineral pyrophyllite alone and in combination, are needed.

Animal studies also often yield useful information concerning dose-response relationships of a compound. Bethe-Iwanske [65] and Wehner [68] both performed animal inhalation studies that may be comparable to human occupational exposure. Experimental problems with both studies, such as the widespread incidence of interstitial pneumonia in the Wehner study, suggest that further animal studies of this nature, at similar concentration levels, are needed. These studies should address the entry and removal of talc from the lungs particularly with regard to the role of the alveolar macrophages and species or gender differences in the clearance response, and further

WCD 001192

development of dose-response relationships.

A number of studies have examined the carcinogenic potential of talc in a variety of species [76,159,75,77,78]. The mutagenic, teratogenic and reproductive effects have not been thoroughly investigated and the mutagenic studies that have been done [77] are not definitive. Further studies in these areas are thus needed.

Epidemiology Research

More comprehensive human epidemiologic studies concerning exposure to nonasbestiform talc are also needed. The effects of low level exposures, as measured by personal samplers, on lung function measurements, clinical symptoms of respiratory disease, and roentgenographic pictures should be examined in a prospective study. Studies of this nature should identify smokers as a subgroup, since a preliminary study by Fine [55] indicated that smokers may be affected to a greater extent than nonsmokers. A study with a control group that has been matched for factors that are known to influence pulmonary function measurements, such as height, smoking history, and age would be especially useful in isolating the effects of occupational exposure of a population to talc. Such a study might further develop the multiple regression model and increase the accuracy of the regression coefficients as developed by Fine [55] by basing the statistical analyses on a larger population of exposed workers.

Excesses of cancer, particularly lung and gastric cancer, have been reported in human mortality studies of populations exposed to talc mixtures

WCD 001193

[52,58,52,64]. Exposure of these populations to many possible carcinogens, 4963 including asbestos, confound the findings and suggest that further research in 4964 this important area is needed. Such studies might compare cancer rates in 4965 populations occupationally exposed to relatively pure talc with a carefully 4967 matched control population.

4970 Sampling and Analytical Studies

4973 More studies need to be performed to increase the accuracy, sensitivity, 4974 and precision of the recommended sampling and analytical procedures. Further 4975 research is needed to develop precise, simple, and inexpensive methods to 4976 simultaneously identify and quantify morphology, crystal structure, and 4977 elemental composition.

WCD 001194

1. Kirk-Othmer Encyclopedia of Chemical Technology. New York, Interscience Publishers, 1954, vol 13, p 565

2. Rohl AN, Langer AM, Selikoff IJ, Tordini A, Klimentidis R, Bowes DR, Skinner DL: Consumer talcums and powders--Mineral and chemical characterization. J Toxicol Environ Health 2:255-84, 1976

3. Langer AM: Aspects of mineralogy of talc, in Goodwin A (ed.): Proceedings of the Symposium on Talc held at Washington, DC on 8 May 1973. Springfield, Va, US Dept of Commerce, National Technical Information Service, 1974, pp 62-98 (NTIS PB 234 871)

4. Mulryan HF: Talc, in Kirk-Othmer Encyclopedia of Chemical Technology, 2nd rev, New York, Interscience Publishers, 1969, vol 19, pp 608-14

5. Luchtrath H, Schmidt KG: [Relation of talc and steatite to asbestos and their effects in intratracheal animal experimentation on rats.] Beitr Silikose-Forsch 60:7-60, 1959 (Ger)

6. Talc, Soapstone, and Pyrophyllite, preprint from Bulletin No. 667. US Dept of Interior, Bureau of Mines, 1975, 12 pp

7. Roe LA: Talc and pyrophyllite, in Industrial Minerals and Rocks. Salt Lake City, Utah, Society of Mining Engineers of AIME, 1948, pp 1127-47

WCD 001195

5043 8. Weiss W, Boettner EA: Commercial talc and talcosis. Arch Environ
5045 Health 14:304-08, 1967

5052 9. McCrone LM: Analysis of Talc by X-ray Diffraction and Polarized Light
5054 Microscopy. Cincinnati, OH Dept of Health, Education, and Welfare, Public
5055 Health Service, Center for Disease Control, National Institute for
5056 Occupational Safety and Health, 1977, 55 pp

5058 10. Sherol CD: Soapstone silicosis--A contribution to the pathological
5059 anatomy of silicosis. Beitr Pathol Anat Allg Pathol 20:85-101 (Ger)

5066 11. Carozzi L: Occupation and Health. Geneva, International Labor Office,
5068 1934, p 1005

5075 12. Zanelli A: [Pneumoconiosis from talc used in a tire factory.] Med Lav
5077 22:3-16, 1931 (Ita)

5083 13. Haynes S: Experimental dust inhalation in guinea-pigs. J Hyg 31:96-
5085 123, 1931

5092 14. Policard A: [Action of talc dust on the lungs--Experimental studies.]
5094 Arch Mal Prof Hyg Toxicol Ind 2:530-39, 1939-40 (Fre)

5100 15. Antopol W. Lycopodium granuloma--its clinical and pathologic
5101 significance together with a note on granuloma produced by talc. Arch Pathol
5102 15:826-31, 1933

5106 16. Flamberg R. Talcum powder granuloma. Arch Pathol 24:36-42, 1937

5117 17. Schulz RZ, Williams CH. Commercial talc--Animal and mineralogical
5118 studies. J Ind Hyg Toxicol 24:75-79, 1942

5125 18. Threshold Limit Values for Chemical Substances and Physical Agents in
5126 the Workroom Environment with Intended Changes for 1977. Cincinnati, American
5127 Conference of Governmental Industrial Hygienists, 1977, p 53

5130 19. Friestedt B, Mattsson SB, Schutz A. [Talcosis by exposure to granular
5131 talc in a rubber industry.] Nord Hyg Tidskr 49:66-71, 1968 (Swe)

5138 20. Scansetti G, Gaido PC, Masetti L. [Data on talcum pneumoconiosis.] Med
5140 Lav 54:650-62, 1963 (Ita)

5145 21. Moskowitz M. Talc pneumoconiosis--A treated case. Chest 58:37-41,
5147 1970

WCD 001197

5154 22. Miller A, Teirstein AS, Bader ME, Bader RA, Selikoff IJ: Talc
5155 pneumoconiosis--Significance of subtight microscopic mineral particles. Am J
5157 Med 50:395-402, 1971

5163 23. Nam K, Gracey DR: Pulmonary talcosis from cosmetic talcum powder. J Am
5165 Med Assoc 221:492-93, 1972

5172 24. Paoli F, Brandi L: [Five cases of talc inhalation.] Minerva Pediatr
5174 22:1772-74, 1970 (Ital)

5180 25. Hughes MT, Kalmer T: Massive talc aspiration--Successful treatment with
5181 dexamethasone. Am J Dis Child 111:653-54, 1966

5189 26. Coulo SR, Barnardo DE: Respiratory distress after talc inhalation. Br
5191 J Dis Chest 66:230-33, 1972

5198 27. Lund JS, Feldt-Rasmussen M: Accidental aspiration of talc--Report of a
5200 case in a two-year-old child. Acta Paediatr Scand 58:295-96, 1969

WCD 001198

5215 28. Weiner JJ, Nathanson G, Eckerg SI Fatal aspiration of talcum powder by
5216 a child--Report of a case. N Engl J Med 266:36-37, 1962

5224 29. Weimann N, Vidailhet M, Kiffer H, Crance JP, Grun G, André JL:
5225 (Accidental inhalation of talcum powder by infants--In connection with two
5226 case studies.) Pediatrie 26:81-84, 1971 (Fre)

5232 30. Class D, Anger M: (Death from suffocation as a result of the inhalation
5233 of baby powder.) Klinerzerzti Prax 22:506-08, 1954 (Ger)

5240 31. Jenkins MO: Dusting powder inhalation. J SC Med Assoc 59:62, 1963

5249 32. Dreesman WC: Effects of certain silicate dusts on the lungs. J Ind Hyg
5251 15:66-78, 1933

WCD 001196

5258 33. Dreesson WC, DallaValle JM: The effects of exposure to dust in two
5259 Georgia talc mills and mines. Public Health Rep 50:131-43, 1935

5266 34. Siegel M, Smith AB, Greenburg L: Report on study of talc miners and
5267 millers in St. Lawrence County, New York. Ind Bull NY State Dep Labor
5269 22:434-37,468-69, 1943

5274 35. Kleinfeld M, Messite J, Tabershaw IR: Talc pneumoconiosis. AMA Arch
5276 Ind Health 12:66-72, 1955

5279 36. Kleinfeld M, Messite J, Shapiro J, Swencicki R: Effect of talc dust
5280 inhalation on lung function. Arch Environ Health 10:431-37, 1965

5288 37. Kleinfeld M, Giel CP, Majarahouski JF, Messite J: Talc pneumoconiosis:
5289 A report of six patients with postmortem findings. Arch Environ Health 7:10
5290 15, 1963

5297 38. Kleinfeld M, Messite J, Kooyman O, Shapiro J: Pulmonary ventilatory
5298 function in talcosis of lung. Dis Chest 46:592-98, 1964

5305 39. Kleinfeld M, Messite J, Shapiro J, Swencicki R, Serfaty J: Lung
5306 function changes in talc pneumonoconiosis. J Occup Med 7:12-17, 1965

40. Kleinfeld M, Messite J, Shapiro J, Kooyman O, Szanciski W: Lung function in talc workers--A comparative physiologic study of workers exposed to fibrous and granular talc dusts. Arch Environ Health 9:559-66, 1964

41. Athyleatos GP, Pentikakis AE, Terzis BG: Talcosis of unusually rapid development. Br J Ind Med 12:43-49, 1955

42. El-Ghawabi SH, El-Sawaf GH, Mahassab HG: Talc pneumoconiosis. J Egypt Med Assoc 53:330-40, 1970

43. Mackay WA, Gibson JB: Siliceous granuloma due to talc--A cause of post-operative peritoneal adhesions. Br Med J 1:1077-78, 1948

44. McCallum DI, Hall GWM: Umbilical granulomata--With particular reference to talc granuloma. Br J Dermatol 83:151-56, 1970

45. Tye MJ, Hashimoto K, Fox FG: Talc granulomas of the skin. J Am Med Assoc 198:1370-72, 1966

WCD 001201

5367 46. Handa K, Ishikawa Y, Shiba Y: [A case of papilloma of the conjunctiva
5368 caused by baby powder.] Folia Ophthalmol Jap 20:645-50, 1969 (Jpn)

5375 47. Morliss WB: Talc treated rice and Japanese stomach cancer. Asian Med J
5377 15:29-32, 1972

5384 48. Hirohata T, Kuratsune M: The geographical comparison of mortality from
5385 cancer of the stomach and ulcer of the stomach in Japan. Br J Cancer 23:465-
5387 79, 1969

5392 49. Matsudo H, Hodgkin WW, Tanaka A: Japanese gastric cancer--Potentially
5394 carcinogenic silicates (talc) from rice. Arch Pathol 97:366-68, 1974

5402 50. Mooley FD: Talc and gastric cancer. Arch Pathol Lab Med 100:110, 1976

5411 51. Henderson WJ, Joslin CAF, Turnbull AC, Griffiths K: Talc and carcinoma
5412 of the ovary and cervix. J Obstet Gynaecol Br Commonw 78:266-72, 1971

5420 52. Selevan SG, Dement JM, Wagoner JK, Holmes JH: Mortality patterns among
5421 miners and millers of non-asbestiform talc. Presented before the Society for

WCD 001202

Occupational and Environmental Health Meeting on Occupational Exposures to
Fibrous and Particulate Dust and Their Extension into the Environment."
Washington, D.C., December 5-7, 1977, 34 pp

53. Rubino GF, Scansetti G, Piolatto G, Romano CA: Mortality study of talc
miners and millers. J Occup Med 18:186-92, 1976

54. Rubino GF, Scansetti G, Piolatto G, Gay G: Mortality and Morbidity
Among Talc Miners and Millers in Italy. Torino, Italy, Institute of
Occupational Health of Turin University, 1977, 12 pp

55. Fine LJ, Peters JM, Burgess WA, Di Berardinis LJ: Studies of
respiratory morbidity in rubber workers--Part IV. Respiratory morbidity in
talc workers. Arch Environ Health 31:195-200, 1976

56. Fine LJ, Peters JM: Respiratory morbidity in rubber workers--I.
Prevalence of respiratory symptoms disease in curing workers. Arch Environ
Health 31:5-9, 1976

57. Wagman DH, Burgess WA, Peters JM: Talc Workers Health Study Report.
Boston, Harvard University, School of Public Health, 1977, 52 pp

58. Mazzitello J, Reddin G, Kleinfeld M: Pulmonary talcosis, a clinical
experimental study. AMA Arch Ind Health 20:408-13, 1959

59. Dement JM, Gamble JF, Brown D, Wagoner JK: Health Aspects Related to
Miners and Millers Occupationally Exposed to Asbestiform Talc. Cincinnati,
US Dept of Health, Education, and Welfare, Public Health Service, Center for
Disease Control, National Institute for Occupational Safety and Health,
Division of Surveillance, Hazard Evaluations and Field Studies, 1975, 125 pp

60. O'Dell HT, Kay JA, Taylor LE: The prevention of peritoneal adhesions and
talc granulomata by cortisone. Surg Forum, 1952, pp 524-31

61. Hunt AC: Massive pulmonary fibrosis from the inhalation of talc.
Thorax 11:287-94, 1956

WCD 001203

5480 62. Wilby FH. In Gafafer WM (ed.): Occupational Diseases--A Guide to Their
5481 Recognition, PHS Publication No. 1097. US Dept of Health, Education, and
5482 Welfare, Public Health Service, 1966, pp 45-48

5485 63. Kleinfeld M, Messite J, Kooyman O, Zaki MH: Mortality among talc miners
5486 and millers in New York State. Arch Environ Health 14:663-67, 1967

5494 64. Kleinfeld M, Messite J, Zaki MH: Mortality experiences among talc
5495 workers--A follow-up study. J Occup Med 16:345-49, 1974

5498 65. Bethge-Iwanska J: [Pathomorphological changes in the respiratory system
5499 in experimental talcosis.] Med Pr 22:45-57, 1971 (Pol)

5506 66. Wehner AP, Zeicker OA, Cannon WC: Inhalation of talc baby powder by
5507 hamsters. Food Cosmet Toxicol 15:121-29, 1977

5515 67. Schepers GWH, Durkan TM: An experimental study of the effects of talc
5516 dust on animal tissue. AMA Arch Ind Health 12:317-28, 1955

5519 68. Gross P, deTreville RTP, Cralley LJ, Granquist OT, Pundsack FL: The
5521 pulmonary response to fibrous dusts of diverse compositions. Am Ind Hyg Assoc
5522 J 31:125-32, 1970

5527 69. Berman EM: Dusting powder granulomas following surgery. Surg Gynec
5529 Obst 76:501-07, 1943

WCD 001204

70. Saxen A, Tuovinen PI: Experimental and clinical observations on granulomas caused by talc and some other substances. Acta Chir Scand 96:131-51, 1947

71. Graham JDP, Jenkins WE: The effects of introducing certain suggested substitutes for talc into peritoneal cavity and into wounds in experimental animals. J Pharm Pharmacol 4:392-98, 1952

72. Aehner AP, Wilkerson CL, Cannon KC, Buschbom RL, Tanner TN: Pulmonary deposition, translocation and clearance of inhaled neutron-activated talc in hamsters. Food Cosmet Toxicol 15:213-24, 1977

73. Phillips JC, Young PJ, Hardy K, Gandolfi SD: Studies on the absorption and disposition of ^{99m}Tc-labelled talc in the rat, mouse, guinea-pig and rabbit. Food Cosmet Toxicol 16:161-63, 1978

74. Aehner AP, Tanner TN, Buschbom RL: Absorption of ingested talc by hamsters. Food Cosmet Toxicol 15:453-55, 1977

75. Pott F, Friedrichs KH, Huth F: (Results from animal experiments on the carcinogenic activity of fibrous dusts and their interpretation in regard to human risk.) Zentralbl Bakteriol Parasitenkd Infektionskr Hyg Abt 1 Orig Reich B 162:467-505, 1976 (Ger)

76. Smith WE: Experimental studies on biological effects of tremolite talc on hamsters. Presented before the Symposium on Talc Dust Hazards, held at Washington, DC, May 8, 1973, 13 pp

WCD 001205

5593 77. Mutagenic Evaluation of Compound FDA 71-43 (1974)--Talc. Springfield,
5594 Va, US Dept of Commerce, National Technical Information Service, 1974, 100 pp
5595 (NTIS PB 245 458)

5602 78. Teratologic Evaluation of FDA 71-43 (Talc). Springfield, Va, US Dept of
5603 Commerce, National Technical Information Service, 1973, 15 pp (NTIS PB 223
5604 828)

5611 79. Davis JMG: The fibrogenic effects of mineral dusts injected into the
5613 pleural cavity of mice. Br J Exp Pathol 53:190-201, 1972

5620 80. Anderson D, Ayer H, Bailer E, Balzer JL, Ettinger HJ, Knight G, Kunkler
5621 K, Lanje P, Laskin S, Lippmann M, Mercer T, Morse KS: Guide for respirable
5622 mass sampling. Am Ind Hyg Assoc J 31:133-37, 1970

5629 81. Gardner LU: Reaction of the living body to different types of mineral
5630 dusts with and without complicating infection. Technical Publication No.
5632 929. New York, American Institute of Mining Metallurgical Engineers Inc,
5633 1938. 15 pp

5638 82. DeGuelare G: Dust Sampling in Mines, Occupational Safety and Health
5639 Series No. 9. Geneva, International Labour Office, 1967, 80 pp

5647 83. Morrow PE: Evaluation of inhalation hazards based upon the respirable
5648 dust concept and the philosophy and application of selective sampling. Ind
5650 Hyg J 25:213-36, 1964

5656 84. Littlefield JB, Feicht FL, Schrenk HH: Bureau of Mines Midget Impinger
5657 for Dust Sampling. Bureau of Mines RI 3360. US Dept of the Interior, Bureau
5659 of Mines, 1937, 4 pp

5665 85. Greenburg L, Bicomfield JJ: The impinger dust sampling apparatus as
5668 used by the US Public Health Service. US Public Health Serv 47:654-75, 1932

5674 86. Hatch T, Warren H, Drinker P: Modified form of the Greenburg-Smith
5675 impinger for field use, with a study of its operating characteristics. J Ind
5677 Hyg 18:8, 1932

5683 87. Kitto PH: Methods of dust measurement. In Oranstein AF (ed.):
5686 Pneumoconiosis--Proceedings of the International Conference, Johannesburg,
5687 Sept 9-24, 1959. Boston, Little, Brown and Co, 1960, pp 13-20

5692 88. Owens JS: Suspended impurity in the air. Proc Roy Soc London Ser A
5694 101:318-37, 1922

WCD 001207

89. Ayer HE, Sutton GW, Davis HH: Size-selective gravimetric sampling in dusty industries. Am Ind Hyg Assoc J 29:334-42, 1968

90. Gurney SR, Williams CH, Meigs HH: Investigation of characteristics of Bausch and Lomb dust counter. J Ind Hyg Toxicol 20:24-35, 1938

91. May KR: The cascade impactor--An instrument for sampling coarse aerosols. J Sci Instrum 22:187-95, 1945

92. Mercer TT: On the calibration of cascade impactors. Ann Occup Hyg 6:1, 1963

93. Cohen JJ, Nonten DN: Theoretical considerations, design, and evaluation of a cascade impactor. Am Ind Hyg Assoc J 28:95-104, 1967

94. Couchman JD: Use of cascade impactors for analyzing airborne particles of high specific gravity. In International Symposium on Fission Product Release and Transport Under Accident Conditions, Oak Ridge, Tenn, April 5-7, 1965, USAEC Report No. CONF-650407, vol 2, 1965

95. Walker JR: Inertial and gravitational collectors. In Air Sampling Instruments for Evaluation of Atmospheric Contaminants, ed 4. Cincinnati,

WCD 001208

American Conference of Governmental Industrial Hygienists, 1972, pp D-1 to D-
5757 27

5762 96. Greenburg L, Smith GM: A new instrument for sampling coal dust,
5763 Serial 2392. US Dept Interior, Bureau of Mines, Reports of Investigations,
5765 1922, 3 pp

5771 97. Threshold Limit Values of Airborne Contaminants—Adopted by the ACGIH
5773 for 1971. Cincinnati, American Conference of Governmental Industrial
5775 Hygienists, 1971, p 20

5780 98. Drinker P, Hatch T: Industrial Dust—Hygienic Significance,
5781 Measurement, and Control, ed 2. New York, McGraw-Hill Inc, 1954, pp 147-55

5789 99. Christie AW: The elastic properties of the emphysematous lung and their
5791 clinical significance. J Clin Invest 13:295-321, 1934

5798 100. Determination of atmospheric concentration of fibrosis-producing and
5799 similar dusts—Proposed standard impinger sampling and counting technique, In
5800 Transactions of the Fifth Annual Meeting of the National Conference of
5801 Governmental Industrial Hygienists. Cincinnati, American Conference of
5802 Governmental Industrial Hygienists, Subcommittee on Standard Methods, 1942

5807 101. Appendix A—Uniform method for impinger counting, In Transactions of

WCD 001209

the Thirty-first Annual Meeting of the American Conference of Governmental
5809 Industrial Hygienists, Denver, Colorado, May 11-13, 1969. Cincinnati,
5810 American Conference of Governmental Industrial Hygienists, Joint Committee on
5811 Uniform Methods for Dust Counting, 1969, pp 204-09

5816 102. Recommendations of the Medical Research Council Panels Relating to
5817 Selective Sampling, Minutes of Joint Meeting, London, March 4, 1952. Medical
5818 Research Council, Dust Subcommittee, Industrial Pulmonary Disease Committee,
5819 1952

5825 103. Hatch TF, Gross P: Pulmonary Deposition and Retention of Inhaled
5826 Aerosols. New York, Academic Press, 1964, pp 147-85

5834 104. Hatch T, Nemeon NCL: Influence of particle size in dust exposure. J
5836 Ind Hyg Toxicol 30:172-80, 1948

5843 105. Dutschkowsky J M, Cristallini C: [X-ray study of fibrous minerals--
5844 Chrysotile from Pie de Palo, San Juan, Argentina.] Rev Minera Geol Mineral
5846 3:69-76, 1974 (Spa)

5852 106. Watson WH: Dust sampling to simulate the human lung. Br J Ind Med
5854 10:93-100, 1953

WCD 001210

5861 107. Lippmann M. "Respirable" dust sampling. Am Ind Hyg Assoc J 31:138-59,
5863 1970

5867 108. De La Higuera Torres-Puchol J, Toro Rojas M, Gonzalez Santos P.
5868 [Pulmonary changes induced by cholesterol ingestion and inhalation of talcum
5869 powder in the rabbit.] Rev Clin Esp 140:543-47, 1976 (Spa)

5872 109. Plant observation reports and evaluation. Menlo Park, SRI
5873 International, May 1978 (submitted to NIOSH under Contract No. 210-77-0015)

5881 110. Zumwalde RD, Dement JM. Review and Evaluation of Analytical Methods for
5882 Environmental Studies of Fibrous Particulate Exposures. DHEW (NIOSH)
5883 Publication No. 77-204. Cincinnati, US Dept of Health, Education, and
5884 Welfare, Public Health Service, Center for Disease Control, National
5885 Institute for Occupational Safety and Health, Division of Surveillance,
5886 Hazards Evaluations, and Field Studies, 1977, 66 pp

5890 111. Criteria for a Recommended Standard....Occupational Exposure to
5891 Asbestos. DHEW Publication No. HSM 72-10267. Rockville, MD, US Dept of
5893 Health, Education, and Welfare, Public Health Service, Health Services and
5894 Mental Health Administration, National Institute for Occupational Safety and
5895 Health, 1972, second printing, 130 pp

5898 112. Revised Recommended Asbestos Standard. DHEW (NIOSH) Publication No. 77-
5899 169. Cincinnati, US Dept of Health, Education, and Welfare, Public Health
5901 Service, Center for Disease Control, National Institute for Occupational
5902 Safety and Health, 1976, 96 pp

5904 113. Beaudy WG, Gold K, Burgess WA, Dement JM. Exposure to industrial talc
5905 in Vermont talc mines and mills. Presented before the American Industrial
5906 Hygiene Association Conference, New Orleans, Louisiana, May 26, 1977, 20 pp

5913 114. McCrone WC, McCrone LB. Light microscopy of microfibers-uses and
5914 limitations. In Asher IM, Orath PP (eds.): Symposium on Electron Microscopy

WCD 001211

of Microfibers--Proceedings of the First FDA Office of Science Summer
5917 Symposium. Food and Drug Administration, Office of Science, Bureau of
5918 Biologics, Bureau of Drugs, Bureau of Foods, 1970, pp 37-43

5922 115. Lanzer AP, Rohl AN, Wolff MS, Klimentidis R, Shirley SH: Review of
5923 current techniques for the analysis of fibers in talc. In Asher IM, Grath PO
5924 (eds.): Symposium on Electron Microscopy of Microfibers--Proceedings of the
5926 First FDA Office of Science Summer Symposium. Food and Drug Administration,
5927 Office of Science, Bureau of Biologics, Bureau of Drugs, Bureau of Foods,
5928 1976, pp 28-33

5931 116. Diffractometric powder technique--Electrical characteristics of the
5932 diffractometer. In Klug HP, Alexander LE: X-Ray Diffraction Procedures--For
5934 Polycrystalline and Amorphous Materials, ed 2. New York, John Wiley and
5935 Sons, 1974, pp 330-35,414-15

5939 117. Martin EE: Principles and Practice of X-Ray Spectrometric Analysis, ed
5941 2. New York, Plenum Press, 1975, pp 161-63,389-95,903-45

5948 118. Crable JV, Knott MJ: Application of x-ray diffraction to the
5949 determination of chrysotile in bulk and settled dust samples. Am Ind Hyg
5951 Assoc J 27:383-85, 1966

5957 119. Crable JV, Knott MJ: Quantitative x-ray diffraction analysis of
5958 crocidolite and amosite in bulk or settled dust samples. Am Ind Hyg Assoc J
5960 27:440-53, 1966

5966 120. Keenan RG, Lynch JR: Techniques for the detection, identification and
5967 analysis of fibers. Am Ind Hyg Assoc J 31:587-97, 1970

WCD 001212

5975 121. Samuels A, Burwood CF, Johari O, Magman J Variability in quantitative
5976 measurements of microfibers using electron microscopy. In Asher IM, Grath PP
5977 (eds.): Symposium on Electron Microscopy of Microfibers--Proceedings of the
5978 First FDA Office of Science Summer Symposium. Food and Drug Administration,
5979 Office of Science, Bureau of Biologics, Bureau of Drugs, Bureau of Foods,
5980 1976, pp 52-59

5984 122. Criteria for a Recommended Standard...Occupational Exposure to
5985 Crystalline Silica, DHEW Publication No. (NIOSH) 75-120, Rockville, Md, US
5987 Dept of Health, Education, and Welfare, Public Health Service, Center for
5988 Disease Control, National Institute for Occupational Safety and Health, 1974,
5989 123 pp

5993 123. Nenadic CM, Crable JV: Application of x-ray diffraction to analytical
5994 problems of occupational health. Am Ind Hyg Assoc J 32:529-38, 1971

6001 124. Nenadic CM, Crable JV: Quantitative determination of talc and tremolite
6002 by x-ray diffraction. Cincinnati, US Dept of Health, Education, and Welfare,
6004 Public Health Service, Center for Disease Control, National Institute for
6006 Occupational Safety and Health, 23 pp (unpublished)

6010 125. Rohl AN, Langer AM: Identification and quantitation of asbestos in
6011 talc. Environ Health Perspect 9:95-109, 1974

6019 126. Scholz JV: The detection of chrysotile asbestos at low levels in talc
6021 by differential thermal analysis. Thermochim Acta 8:197-206, 1974

WCD 001213

6028 127. Dirks LS, Fatemi P, Ulfrich JV, Johnson LF: Quantitative Analysis of
6029 Airborne Asbestos by X-ray Diffraction-- Feasibility Study, Report No. AD-
6030 A007530). Naval Research Laboratory, 1975

6037 128. Detection of Asbestiform Amphibole Minerals in Cosmetic Grade Talc,
6038 Method No. J4-1. Washington, DC, Cosmetic, Toiletry, and Fragrance
6039 Association, Standard Committee, Talc Subcommittee, 10 pp (undated)

6046 129. Pease DC: Introduction to electron microscopy, in Asher IM, Grath PP
6048 (eds.): Symposium on Electron Microscopy of Microfibers--Proceedings of the
6049 First FDA Office of Science Summer Symposium. Food and Drug Administration,
6051 Office of Science, Bureau of Biologics, Bureau of Drugs, Bureau of Foods,
6052 1976, pp 44-47

6055 130. Siegal W, Smith AR, Greenburg L: The dust hazard in tremolite talc
6056 mining, including roentgenological findings in talc workers. Am J Roentgenol
6058 Radium Ther 49:11-29, 1943

6061 131. Dement JM, Zumwalde RD: Final Report--Industrial Hygiene Study on the
6062 Gouverneur Talc Company, Number One Mine and Mill--Balmat, New York--Volume
6063 I. Cincinnati, US Dept of Health, Education, and Welfare, Center for Disease
6065 Control, National Institute for Occupational Safety and Health, Division of
6066 Surveillance, Hazard Evaluations and Field Studies, 1977, 79 pp

6069 132. Dement J, Shuler P: Talc Dust and Industrial Hygiene Survey--Plymouth
6070 Rubber Company, Canton, Massachusetts. Cincinnati, US Dept of Health,
6071 Education, and Welfare, Public Health Service, Center for Disease Control,
6072 National Institute for Occupational Safety and Health, Division of Field
6073 Studies and Clinical Investigations, Environmental Investigations Branch,
6075 1978, 15 pp

6077 133. Dement JM, Shuler PJ, Alvarado PF: Reevaluation of Control Measures in
6078 the Rubber Hand Manufacturing Area--Plymouth Rubber Company, Canton,
6079 Massachusetts. Cincinnati, US Dept of Health, Education, and Welfare, Public
6080 Health Service, Center for Disease Control, National Institute for
6081 Occupational Safety and Health, Division of Field Studies and Clinical

WCD 001214

Investigations. Environmental Investigations Branch, 1973, 10 pp

6095 134. Report of Committee on Threshold Limits, in Proceedings of the 8th
6096 Annual Meeting, Chicago, April 7-13, 1946. Cincinnati, American Conference
6097 of Governmental Industrial Hygienists, 1946, p 55

6099 135. Threshold Limit Values Adopted at April, 1948 Meeting of the American
6099 Conference of Governmental Industrial Hygienists in Detroit, Michigan.
6099 Cincinnati, American Conference of Governmental Industrial Hygienists, 1948,
6097 2 pp

6103 136. Threshold Limit Values for 1962--Adopted at the 24th Annual Meeting of
6104 the American Conference of Governmental Industrial Hygiene, Washington, DC,
6105 May 13-15, 1962. Cincinnati, American Conference of Governmental Industrial
6106 Hygienists, 1962, pp 10-11

6112 137. Documentation of Threshold Limit Values. Cincinnati, American
6113 Conference of Governmental Industrial Hygienists, Committee on Threshold
6112 Limit Values, 1962, pp 97-99

6121 138. Perro PK, Patton JW, Hobbs AA Jr. Pneumoconiosis in the talc industry.
6123 Am J Roentgenol Radium Ther 47:537-24, 1942

6129 139. Greenburg L. The dust hazard in tremolite talc mining. Yale J Biol Med
6131 19:481-501, 1947

WCD 001215

6138 140. McLaughlin AIG, Rogers I, Denham KC: Talc pneumoconiosis. Br J Ind Med
6140 6:184-94, 1949

6146 141. Jaques ME, Benirschke K: Pulmonary talcosis with involvement of the
6147 stomach and the heart--Report of a case. AMA Arch Ind Hyg 5:451-63, 1952

6155 142. Friedman PS, Bell MA, Solis-Cohen L: Talc pneumoconiosis. J Am Med
6157 Assoc 148:1418-19, 1952

6164 143. Mann H, Deasy JB: Talc pneumoconiosis in the textile industry. Br Med
6166 J 2:1460-61, 1954

6173 144. Hubner O, Muller G: [Mineralogical and physical-chemical investigations
6174 of talc silicosis and talc skin granulomas.] Arch Gewerbepathol Gewerbehyg
6176 15:446-66, 1957 (Ger)

6181 145. Sealer AD: Toxic hazards--Talc pneumoconiosis. N Engl J Med 261:1084-
6183 85, 1959

WCD 001216

6190 146. Nemir A., Mallette F.S. A study of workers exposed to talc and other
6191 dusting compounds in the rubber industry. J Ind Hyg Toxicol 31:59-64, 1949

6193 147. Threshold Limit Values for 1964—Adopted at the 26th Annual Meeting of
6199 the American Conference of Governmental Hygienists, Philadelphia,
6200 Pennsylvania, April 25-28, 1964. Cincinnati, American Conference of
6201 Governmental Industrial Hygienists, 1964, pp 29-21

6205 148. Threshold Limit Values for 1967—Recommended and Intended Values.
6206 Cincinnati, American Conference of Governmental Industrial Hygienists, 1967,
6207 p 15

6214 149. Documentation of Threshold Limit Values, rev ed. Cincinnati, American
6215 Conference of Governmental Industrial Hygienists, 1966, p 15

6213 150. Threshold Limit Values of Airborne Contaminents and Intended Changes—
6217 Adopted by the ACGIH for 1970. Cincinnati, American Conference of
6219 Governmental Industrial Hygienists, 1970, pp 16-18,26-27

6226 151. Threshold Limit Values of Air-borne Contaminents for 1968—Recommended
6227 and Intended Values. Cincinnati, American Conference of Governmental
6228 Industrial Hygienists, 1968, p 17

6230 152. Threshold Limit Values for Airborne Contaminents—Adopted by ACGIH for
6231 1969 and Intended Changes. Cincinnati, American Conference of Governmental
6232 Industrial Hygienists, 1969, pp 16-19

WCD 001217

6239 153. Threshold Limit Values of Airborne Contaminants--Adopted by the ACGIH
6240 for 1972. Cincinnati, American Conference of Governmental Industrial
6241 Hygienists, 1972, pp 30-31, 38-39

6248 154. TLVs--Threshold Limit Values for Chemical Substances and Physical
6249 Agents in the Workroom Environment with Intended Changes for 1974.
6250 Cincinnati, American Conference of Governmental Industrial Hygienists, 1974,
6251 pp 32-37, 40-41

6257 155. Documentation of Threshold Limit Values for Substances in Workroom Air.
6258 ed 3. Cincinnati, American Conference of Governmental Industrial
6259 Hygienists, Committee on Threshold Limit Values, 197[illegible], pp 242-43, 262

6266 156. Schepers GWH, Durkan TM: The effects of inhaled talc-mining dust on the
6267 human lung. AMA Arch Ind Health 11:182-97, 1955

6275 157. Documentation of the Threshold Limit Values for Substances in Workroom
6276 Air, ed 3, 1971. Cincinnati, American Conference of Governmental Industrial
6277 Hygienists, Committee on Threshold Limit Values, 2nd printing, 1974, pp 242-
6278 43, 262

WCD 001218

6284 158. TLVs--Threshold Limit Values for Chemical Substances and Physical
6285 Agents in the Workroom Environment with Intended Changes for 1977.
6286 Cincinnati, American Conference of Governmental Industrial Hygienists, 1977,
6287 pp 32-39

6293 159. Pott F, Friedrichs KH: [Tumors of the rat developing after
6294 intraperitoneal injection of fibrous dusts.] Naturwissenschaften 59:318,
6295 1972 (Ger)

6301 160. Pask JA, Warner MF: Fundamental studies of talc--I. Constitution of
6302 talcs. J Am Ceram Soc 37:118-28, 1954

6309 161. Steeple IS, Brindley GW: A structural study of talc and talc-tremolite
6310 relations. J Am Ceram Soc 43:34-41, 1960

6317 162. Wells JR: Talc, soapstone and pyrophyllite, in Minerals Yearbook,
6318 1974. New York, American Institute of Mining, Metallurgical, and Petroleum
6319 Engineers Inc, 1974, pp 1261-68

6322 163. Talc, Soapstone and Pyrophyllite, preprint from 1975 Bureau of Mines
6323 Minerals Yearbook. US Dept of Interior, Bureau of Mines, 1975, 7 pp

WCD 001219

Sampling and Analytical Method for Talc (Respirable Dust)

Principle of the Method

(a) A known volume of air is drawn through polyvinyl chloride filters (pre-weighed) preceded by 10 mm nylon cyclone separators to collect respirable dust at a flowrate of 1.7 litres/minute.

(b) The sample-containing filters are removed from the cassette, and weighed with a suitable microbalance.

Range and Sensitivity

With a good microbalance, the lower limit of the working range should be approximately 0.05 mg/sample. There is no upper limit unless the filter is completely overloaded.

Interferences

(a) The presence of any other particulate material in the air being sampled will be a positive interference, since this is a gravimetric method.

(b) Information on any other particulate material present should be solicited. If the concentration of other particulates is known, talc concentration can be determined by subtraction. If other particulate matter is known to be present and its concentration cannot be determined, this method will not provide an accurate measure of talc concentration.

WCD 001220

Advantages and Disadvantages

The recommended method is simple, inexpensive, and requires no bulky equipment. However, it is not specific, since any particulate matter present in the air being sampled will interfere.

Apparatus

(a) Sampling Equipment. The sampling unit for the collection of personal air samples for the determination of respirable talc dust has the following components:

(1) A 10 mm nylon cyclone separator with a bracket for securing the filter cassette.

(2) The filter unit, consisting of a 37-mm polyvinyl chloride filter with a 0.8 (um pore size, a support pad, and a three-piece filter cassette.

(3) The personal sampling pump. Calibrated personal sampling pump whose flow can be determined to an accuracy of 95% at the recommended flowrate of 1.7 liters/minute. The pump must be calibrated with a filter holder and filter in the line.

(b) Thermometer.

(c) Barometer.

(d) Stopwatch.

(e) Soapbubble meter.

(f) A plastic petri dish used as a filter holder for conditioning and weighing.

WCD 001221

(g) Analytical Equipment. A microbalance capable of weighing to 0.05 mg.

Procedure

(a) Preparation of Filters. All filters must be conditioned and weighed before use. Place filters in a desiccator before weighing.

(b) Sampling Requirements

(1) To collect respirable dust a personal sampling pump is used to pull air through a cyclone preseparator and a polyvinyl chloride filter. The filter holder is held together by the cyclone bracket and is directly connected to the outlet of the cyclone preseparator. A piece of flexible tubing is used to connect the filter holder to the pump. Fasten the sampler to the lapel or shirt front, and start the pump to draw air through the sampler at a flowrate of 1.7 liters/minute. After sampling, the filter cassettes are removed from the cyclone and sealed by replacing small plugs at both ends.

(2) With each batch of 10 samples, submit 1 filter from the same lot as that used for sample collection. This filter should be handled the same way as the samples, except that no air should be drawn through it. Label this as a blank.

(c) Shipping of Samples. The filter cassettes should be shipped in a suitable container designed to prevent damage to the filter in transit.

(d) Analysis of Samples

(1) If the outer surface of the cassette filter holder is heavily coated with dust, carefully wash it with a moist paper towel before opening

the cassette to minimize sample contamination. Discard the paper towel.

(2) Open the cassette filter holder and carefully remove the filter from the supporting pad in the holder with the aid of filter tweezers. Transfer filters to a petri dish.

(3) Bring the filter to constant relative humidity in a desiccator.

(4) Weigh the filter with a microbalance.

Calibration and Standards

The microbalance should be properly zeroed for all weighings, and the same microbalance should preferably be used for weighing each filter before and after samples are collected.

Calibration of Sampling Trains

The accurate calibration of sampling pump is essential for the correct interpretation of the volume indicated. The proper frequency of calibration is dependent on the use, care, and handling to which the pump is subjected. Pumps should be recalibrated if they have been subjected to misuse or if they have just been repaired or received from a manufacturer. If the pump receives hard usage, more frequent calibration may be necessary. Maintenance and calibration should be performed on a regular schedule and records of these kept.

Ordinarily, pumps should be calibrated in the laboratory both before they are used in the field, during field procedures, and after they have been used to collect a large number of field samples. The accuracy of calibration is

WCD 001223

dependent on the type of instrument used as a reference. The choice of
calibration instrument will depend largely on where the calibration is to be
performed. For laboratory testing, a soapbubble meter or spirometer is
recommended, although other standard calibrating instruments, such as a wet-
test meter or dry-gas meter, can be used.

Instructions for calibration with the soapbubble meter follow. If another
calibration device is selected, equivalent procedures should be used. Since
the flowrate given by a pump is dependent on the pressure drop of the sampling
device, in this case a polyvinyl chloride filter, the pump must be calibrated
while operating with the representative filters in line. Calibration of the
sampling train should be performed at a pressure of 1 atmosphere.

(a) While the pump is running, check the voltage of the pump battery with
a voltmeter to assure adequate voltage for calibration. Charge the battery if
necessary.

(b) Place the preweighed filter in the filter cassette.

(c) Assemble the sampling train according to the manufacturer's
specifications or as shown in Figure XI-1.

(d) Turn on the pump and moisten the inside of the soapbubble meter by
immersing the buret in the soap solution. Draw bubbles up the inside until
they are able to travel the entire buret length without bursting.

(e) Adjust the pump rotameter to provide a flowrate of 1.7 liters/minute.

(f) Start a soapbubble up the buret and measure with stopwatch the time
it takes the bubble to pass through a minimum of 1 liter.

(g) Repeat the procedure in (f) at least three times, average the

WCD 001224

results, and calculate the flowrate by dividing the volume of air between the
0533 preselected marks by the time required for the soapbubble to traverse the
0534 distance.

0536 (h) Record the following calibration data: volume measured, elapsed
0537 time, air temperature, atmospheric pressure, serial number of the pump, and
0538 name of the person performing the calibration.

0542 Calculations

0545 (a) Record the tare weight, in mg, of the filter before sampling.

0548 (b) Record the weight, in mg, of the filter containing the sample.

0551 (c) The difference between these two weights represents the weight of the
0552 sample in mg.

0554 (d) Corrections for the blank must be made for each sample. If
0555 necessary, corrections should also be made for other particulate matter.

0560 (e) Convert volume of air sampled to standard conditions of 25 C and 760
0561 mmHg

0564 $$Vs = V \times \frac{P}{760} \times \frac{298}{(T + 273)}$$

0567 where:

0569 Vs = volume of air in liters at 25 C and 760 mmHg.
0570 V = volume of air in liters as measured.
0571 P = barometric pressure in mmHg.
0572 T = ambient air temperature in degrees C.

0576 (f) The concentration of talc in the air sampled can be expressed in
0577 mg/cu m (mg per liter = mg/cu m):

WCD 001225

WCD 001226

6581 mc/cu m = fuel flow(l)
6582 Vs

X. APPENDIX II

SAMPLING AND ANALYTICAL METHOD FOR ASBESTOS FIBERS ASSOCIATED WITH TALC DUST IN AIR

Principle of the Method

A known volume of air is drawn through a membrane filter. The fibers and dust particles collected on the filter are fused to a microscopically smooth surface on a glass slide and vacuum-coated with carbon. The sample is then transferred to a carbon-coated electron microscope grid by dissolving away the filter. The grid is submitted to a transmission/scanning electron microscope equipped with an energy-dispersive X-ray spectrometer for identification and counting of asbestos fibers by comparing selected area electron diffraction patterns and microchemical analysis of the fibers.

Range and Sensitivity

The range and sensitivity of this method has not been determined.

Interferences

The identification procedure for asbestos fibers is accurate, so no serious interferences are expected.

Precision and Accuracy

WCD 001227

The precision and accuracy of this method has not been determined.

Advantage and Disadvantages

The combined method of selected area electron diffraction and microchemical analysis permits a positive identification of amphibole fibers in a sample of mixed minerals. Visual characterization of particulate morphology, simultaneous observation of the single-fiber selected area electron diffraction pattern, and fiber chemical composition can be made at the same time. However, this combined method requires expensive equipment and extensive sample preparation. The time required for analysis is also long.

Apparatus

(a) Sampling Equipment.

The sampling unit for collection of personal air samples for the determination of asbestos fibers associated with talc dust has the following components:

(1) The filter unit, consisting of a 37-mm membrane filter, filter support pad, and a three-piece cassette filter holder.

(2) A calibrated personal sampling pump whose flow can be determined to an accuracy of ±5% at the recommended flowrate of 2 liters/minute.

(b) Analytical Equipment

(1) Transmission/scanning electron microscope equipped with an energy-dispersive X-ray spectrometer.

(2) Vacuum evaporator for carbon-coating of fused filter.

WCD 001228

(5) Carbon tip, 5 mm in length and 1 mm in diameter.

(4) Petri dish.

(5) Whatman filter.

(6) Electron microscope grid, 200-mesh.

(7) Cork bore, scalpel, and tweezers.

(8) Glass slide.

(c) Reagents

(1) Acetone.

(2) Formvar.

(d) Calibration Equipment

(1) Thermometer.

(2) Manometer.

(3) Stopwatch.

(4) Soapbubble meter.

Procedure

(a) Sampling

(1) Place a membrane filter in a 3-piece filter cassette or holder. Connect the holder and the personal sampling pump with flexible tubing. Mount the pump to the worker's belt and clip the filter holder to the lapel or shirt front as close to the breathing zone as is practible.

(2) Remove the top cover of the plastic filter holder, then invert the holder making certain the exposed filter is facing downward. Turn the pump on and adjust the flowrate to 2 liters/minute.

WCD 001229

(3) After sampling, replace the plastic top cover and the small end plug. Keep the filters in their holder and prepare them for shipping to a laboratory for analysis.

(4) With each batch of 20 samples, submit 2 filter from each batch of the filters to the laboratory for a blank count. The blank filters should be given the same handling treatment as those used to collect air samples, except that the blanks should not be exposed.

(b) Sample Preparation

(1) Cut out a section of the filter with an 8-mm diameter cork bore or a scalpel.

(2) Remove the cut-out section and place it, sample side up, on a clean microscope slide. Use aumed binder ring to fasten the circular section of filter to the slide, or use thin strip of transparent tape to fasten the scalpel-cut section.

(3) Put four dhatman filters in a covered petri dish and saturate them with acetone. Place the slide assembly on top of the acetone-saturated filters for 2-15 minutes to dissolve away the microporous structure of the membrane filter. This will produce a fused and microscopically smooth surface on the sample side of the membrane filter.

(4) After the filter has been fused, place the slide assembly in a vacuum evaporator on a rotary stage, where the sampled side of the filter is to be coated with carbon. The tip of the carbon rod should be placed perpendicular to and approximately 10 cm from the center of the filter section.

WCD 001230

(5) Place four Whatman filters in covered petri dish and saturate with acetone. Put several 200-mesh formvar/carbon-coated electron microscope grids right side up on the Whatman filters.

(6) Cut sections somewhat larger than the grids from the coated membrane filter and placed, sample side down, on the electron microscope grid. Care must be taken to prevent the coated membrane filter section from curling or shrivelling when it is placed on the grid.

(7) Let the membrane filter-grid-Whatman filter assembly stand for 8-16 hours for complete dissolution of the filter matrix by the acetone vapor. Saturation of Whatman filters should be maintained for this period. After this step, only the particulates adhering to the carbon film is left on the grids.

(c) Identifying and Counting of Asbestos Fibers

(1) Place the prepared grid with sample on it in the transmission electron microscope.

(2) Scan the grid to assure even distribution of particulates and to ascertain the quality and suitability of the sample preparation. Select a proper magnification for observation.

(3) Perform selected area electron diffraction (SAED) on particulates having a length-to-width ratio of greater than or equal to 3:1. Determine which fiber has a positive amphibole diffraction pattern, positive chrysotile diffraction pattern, nonasbestos diffraction pattern, amorphous pattern, or no SAED pattern.

(4) Perform microchemical analysis on the fibers displaying the

WCD 001231

spectrum on the video display. The elemental ratios are compared and the fibrous minerals identified by comparison with known standards.

(5) Size the identified fiber with calibrated circles or millimeter markings etched on the viewing screen.

(6) Selected pictures of microchemical analysis and/or SAED patterns are taken and stored for later reference.

(7) Fiber concentrations are calculated using the average grid opening area as the counting field area. At least, 10 grid openings or 50 fibers should be counted and analyzed from each sample. Dimensions of at least five grid openings should be measured using an optical microscope.

(d) Calibration and Standards

Although the WICC standards can be used for calibration purposes, the bulk minerals from which talc is used in a workplace is a more reliable standard. Therefore, bulk quantities of the sampled minerals should be obtained and characterized.

(e) Calibration of Sampling Train

The accurate calibration of a sampling pump is essential for the correct interpretation of the volume indicated. The proper frequency of calibration is dependent on the use, care, and handling to which the pump is subjected. Pumps should be recalibrated if they have been subjected to misuse or if they have just been repaired or received from a manufacturer. If the pump receives hard usage, more frequent calibration may be necessary. Maintenance and calibration should be performed on a regular schedule and records of these kept.

WCD 001232

Ordinarily, pumps should be calibrated in the laboratory both before they are used in the field, during field procedures, and after they have been used to collect a large number of field samples. The accuracy of calibration is dependent on the type of instrument used as a reference. The choice of calibration instrument will depend largely on where the calibration is to be performed. For laboratory testing, a soapbubble meter or spirometer is recommended, although other standard calibrating instruments, such as a wet-test meter or dry-gas meter, can be used.

Instructions for calibration with the soapbubble meter follow. If another calibration device is selected, equivalent procedures should be used. Since the flowrate given by a pump is dependent on the pressure drop of the sampling device, in this case a membrane filter, the pump must be calibrated while operating with the representative filter in line. Calibration of the sampling train should be performed at pressure of 1 atmosphere.

(1) While the pump is running, check the voltage of the pump battery with a voltmeter to assure adequate voltage for calibration. Charge the battery if necessary.

(2) Place a filter in the filter cassette.

(3) Assemble the sampling train according to the manufacturer's specifications or as shown in Figure XII-1.

(4) Turn on the pump and moisten the inside of the soapbubble meter by immersing the buret in the soap solution. Draw bubbles up the inside until they are able to travel the entire buret length without bursting.

(5) Adjust the pump rotameter to provide a flowrate of 2

WCD 001233

liters/minute.

(c) Start a soapbubble up the buret and measure with stopwatch the time it takes the bubble to pass through a minimum of 1.0 liter.

(d) Repeat the procedure in (c) at least three times, average the results, and calculate the flowrate by dividing the volume of air between the preselected marks by the time required for the soapbubble to traverse the distance.

(e) Record the following calibration data: volume measured, elapsed time, air temperature, atmospheric pressure, serial number of the pump, date, and name of the person performing the calibration.

Calculation

(a) Record the number of asbestos of fibers identified and counted, in both the sampled and blank filters.

(b) Record the number of grid openings counted, in both the sampled and blank filters.

(c) Convert volume of air sampled to standard conditions of 25 C and 760 mmHg

$$Vs = V \times \frac{P}{760} \times \frac{298}{(T + 273)}$$

where:

Vs = Volume of air sampled in liters at 25 C and 760 mmHg

V = Volume of air in liters as sampled

WCD 001234

P = Barometric pressure in mmHg

T = ambient air temperature in C

(d) The concentration of asbestos fibers in air samples can be calculated from

$$AC = \frac{(FC - FB) \times EA}{N \quad B} \Big/ Vs \times A \times 1000$$

where:

AC = Asbestos fiber concentration in air, number of fibers/cc

FC = total number of asbestos fibers counted in sample grids

N = total number of grid openings counted for sample

FB = total number of asbestos fiber counted in blank

B = total number of grid openings counted for blank

A = average area of grid opening, sq mm

EA = Effective area of the filter, sq mm

Vs = Volume of air sampled in liters at 25 C and 760 mmHg

WCD 001235

MATERIAL SAFETY DATA SHEET

The following items of information which are applicable to a specific product or material shall be provided in the appropriate block of the Material Safety Data Sheet (MSDS).

The product designation is inserted in the block in the upper left corner of the first page to facilitate filing and retrieval. Print in upper case letters as large as possible. It should be printed to read upright with the sheet turned sideways. The product designation is that name or code designation which appears on the label, or by which the product is sold or known by employees. The relative numerical hazard ratings and key statements are those determined by the rules in Chapter V, Part B, of the NFPA/HMIS publication, An Identification System for Occupationally Hazardous Materials. The company identification may be printed in the upper right corner if desired.

(a) Section I. Production Identification

The manufacturer's name, address, and regular and emergency telephone numbers (including area code) are inserted in the appropriate blocks of Section I. The company listed should be a source of detailed backup information on the hazards of the material(s) covered by the MSDS. The listing of suppliers or wholesale distributors is discouraged. The trade name should be the product designation or common name associated with the material.

WCD 001236

The synonyms are those commonly used for the product, especially formal chemical nomenclature. Every known chemical designation or competitor's trade name need not be listed.

(b) Section II. Hazardous Ingredients

The "materials" listed in Section II shall be those substances which are part of the hazardous product covered by the MSDS and individually meet any of the criteria defining a hazardous material. Thus, one component of a multicomponent product might be listed because of its toxicity, another component because of its flammability, while a third component could be included both for its toxicity and its reactivity. Note that a MSDS for a single component product must have the name of the material repeated in this section to avoid giving the impression that there are no hazardous ingredients.

Chemical substances should be listed according to their complete name derived from a recognized system of nomenclature. Where possible, avoid using common names and general class names such as "aromatic amine," "safety solvent," or "aliphatic hydrocarbon" when the specific name is known.

The "%" may be the appropriate percentage by weight or volume indicate basis which each hazardous ingredient of the mixture bears to the whole mixture. This may be indicated as a range or maximum amount, ie. "10-60% vol" or "10% max wt" to avoid disclosure of trade secrets.

Toxic hazard data shall be stated in terms of concentration, mode of exposure or test, and animal used, ex. "100 ppm LC50-rat," "25 mc/kr LD50-skin-rabbit," "75 ppm LC man," or "permissible exposure from 29 CFR

WCD 001237

(910.1CO$_2$" or, if not available, from other sources of publications such as the American Conference of Governmental Industrial Hygienists or the American National Standards Institute Inc. Flashpoint, shock sensitivity, or similar descriptive data may be used to indicate flammability, reactivity, or similar hazardous properties of the material.

(c) Section III. Physical Data

The data in Section III should be for the total mixture and should include the boiling point and melting point in degrees Fahrenheit (Celsius in parentheses)) vapor pressure, in conventional millimeters of mercury (mmHg)) vapor density of gas or vapor (air = 1)) solubility in water, in parts/hundred parts of water by weight specific gravity (water = 1)) percent volatiles (indicated if by weight or volume) at 70 degrees Fahrenheit (21.1 degrees Celsius)) evaporation rate for liquids or sublimable solids, relative to butyl acetate)) and appearance and odor. These data are useful for the control of toxic substances. Boiling point, vapor density, percent volatiles, vapor pressure, and evaporation are useful for designing proper ventilation equipment. This information is also useful for design and deployment of adequate fire and spill containment equipment. The appearance and odor may facilitate identification of substances stored in improperly marked containers, or when spilled.

(d) Section IV. Fire and Explosion Data

Section IV should contain complete fire and explosion data for the product, including flashpoint and autoignition temperature in degrees Fahrenheit (Celsius in parentheses)) flammable limits, in percent by volume in

WCD 001238

air suitable extinguishing media or material; special firefighting
procedures and unusual fire and explosion hazard information. If the product
presents no fire hazard, insert "NO FIRE HAZARD" on the line labeled
"Extinguishing Media."

(e) Section V. Health Hazard Information

The "Health Hazard Data" should be a combined estimate of the hazard of
the total product. This can be expressed as a TWA concentration, as a
permissible exposure, or by some other indication of an acceptable standard.
Other data are acceptable, such as lowest LD50 if multiple components are
involved.

Under "Routes of Exposure," comments in each category should reflect the
potential hazard from absorption by the route in question. Comments should
indicate the severity of the effect and the basis for the statement if
possible. The basis might be animal studies, analogy with similar products,
or human experiences. Comments such as "yes" or "possible" are not helpful.
Typical comments might be:

Skin Contact--single short contact, no adverse effects likely;
prolonged or repeated contact, possibly mild irritation.

Eye Contact--some pain and mild transient irritation; no
corneal scarring.

"Emergency and First Aid Procedures" should be written in lay language and
should primarily represent first-aid treatment that could be provided by
paramedical personnel or individuals trained in first aid.

Information in the "Notes to Physician" section should include any special

WCD 001239

medical information which could be of assistance to an attending physician
including required or recommended preplacement and periodic medical
examinations, diagnostic procedures, and medical management of overexposed
employees.

(f) Section VI. Reactivity Data

The comments in Section VI relate to safe storage and handling of
hazardous, unstable substances. It is particularly important to highlight
instability or incompatibility to common substances or circumstances, such as
water, direct sunlight, steel or copper piping, acids, alkalies, etc.
"Hazardous Decomposition Products" shall include those products released under
fire conditions. It must also include dangerous products produced by aging,
such as peroxides in the case of some ethers. Where applicable, shelf life
should also be indicated.

(g) Section VII. Spill or Leak Procedures

Detailed procedures for cleanup and disposal should be listed with
emphasis on precautions to be taken to protect employees assigned to cleanup
detail. Specific neutralizing chemicals or procedures should be described in
detail. Disposal methods should be explicit including proper labeling of
containers holding residues and ultimate disposal methods such as "sanitary
landfill" or "incineration." Warnings such as "comply with local, state, and
Federal antipollution ordinances" are proper but not sufficient. Specific
procedures shall be identified.

(h) Section VIII. Special Protection Information

Section VIII requires specific information. Statements such as "Yes,"
"No," or "If necessary" are not informative. Ventilation requirements should

WCD 001240

7098 be specific as to type and preferred methods. Respirators shall be specified
7099 as to type and NIOSH or US Bureau of Mines approval class, ie, "Supplied air,"
7100 "Organic vapor canister," etc. Protective equipment must be specified as to
7101 type and materials of construction.

7104 (i) Section IX. Special Precautions

7107 "Precautionary Statements" shall consist of the label statements selected
7108 for use on the container or placard. Additional information on any aspect of
7109 safety or health not covered in other sections should be inserted in Section
7110 IX. The lower block can contain references to published guides or in-house
7111 procedures for handling and storage. Department of Transportation markings
7112 and classifications and other freight, handling, or storage requirements and
7113 environmental controls can be noted.

7116 (j) Signature and Filing

7119 Finally, the name and address of the responsible person who completed the
7120 MSDS and the date of completion are entered. This will facilitate correction
7121 of errors and identify a source of additional information.

7123 The MSDS shall be filed in a location readily accessible to employees
7124 exposed to the hazardous substance. The MSDS can be used as a training aid
7125 and basis for discussion during safety meetings and training of new employees.
7126 It should assist management by directing attention to the need for specific
7127 control engineering, work practices, and protective measures to ensure safe
7128 handling and use of the material. It will aid the safety and health staff in
7129 planning a safe and healthful work environment and in suggesting appropriate
7130 emergency procedures and sources of help in the event of harmful exposure of

WCD 001241

1910.1002," or, if not available, from other sources of publications such as the American Conference of Governmental Industrial Hygienists or the American National Standards Institute Inc. Flashpoint, shock sensitivity, or similar descriptive data may be used to indicate flammability, reactivity, or similar hazardous properties of the material.

(d) Section III. Physical Data

The data in Section III should be for the total mixture and should include the boiling point and melting point in degrees Fahrenheit (Celsius in parentheses); vapor pressure, in conventional millimeters of mercury (mmHg); vapor density of gas or vapor (air = 1); solubility in water, in parts/hundred parts of water by weight; specific gravity (water = 1); percent volatiles (indicated if by weight or volume) at 70 degrees Fahrenheit (21.1 degrees Celsius); evaporation rate for liquids or sublimable solids, relative to butyl acetate; and appearance and odor. These data are useful for the control of toxic substances. Boiling point, vapor density, percent volatiles, vapor pressure, and evaporation are useful for designing proper ventilation equipment. This information is also useful for design and deployment of adequate fire and spill containment equipment. The appearance and odor may facilitate identification of substances stored in improperly marked containers, or when spilled.

(e) Section IV. Fire and Explosion Data

Section IV should contain complete fire and explosion data for the product, including flashpoint and autoignition temperature in degrees Fahrenheit (Celsius in parentheses); flammable limits, in percent by volume in

WCD 001242

air suitable extinguishing media or materials; special firefighting
procedures; and unusual fire and explosion hazard information. If the product
presents no fire hazard, insert "NO FIRE HAZARD" on the line labeled
"Extinguishing Media."

(e) Section V. Health Hazard Information

The "Health Hazard Data" should be a combined estimate of the hazard of
the total product. This can be expressed as a TWA concentration, as a
permissible exposure, or by some other indication of an acceptable standard.
Other data are acceptable, such as lowest LD50 if multiple components are
involved.

Under "Routes of Exposure," comments in each category should reflect the
potential hazard from absorption by the route in question. Comments should
indicate the severity of the effect and the basis for the statement if
possible. The basis might be animal studies, analogy with similar products,
or human experiences. Comments such as "yes" or "possible" are not helpful.
Typical comments might be:

Skin Contact--single short contact, no adverse effects likely;
prolonged or repeated contact, possibly mild irritation.

Eye Contact--some pain and mild transient irritation; no
corneal scarring.

"Emergency and First Aid Procedures" should be written in lay language and
should primarily represent first-aid treatment that could be provided by
paramedical personnel or individuals trained in first aid.

Information in the "Notes to Physician" section should include any special

WCD 001243

WCD 001244

employees.

TALC FIRST DRAFT

XII. TABLES AND FIGURES

TABLE XII-1

MINERALOGICAL AND CHEMICAL PROPERTIES OF TALC

Empirical formula	$3MgO \cdot 4SiO_2 \cdot H_2O$
Formula weight	63.5% SiO_2, 31.7% MgO, 4.8% H_2O
Appearance	Platy, soft, exhibiting a high degree of lubricity (slip) to fibrous, hydrophobic surface properties, slippery feel
Moh's scale of hardness	1, maybe harder with impurities
Color	Snow-white (pure) to greenish gray and various shades of green (with impurities)
Specific gravity	2.58-2.83
X-ray unit cell dimensions	a=5.27±0.02a.u.; b=9.13±0.03a.u.; c=18.96±0.05a.u.; β=100 15'±15'
DTA endothermic peak (Differential Thermal Analysis)	965 C
Refraction index	1.54-1.59
Crystal form	Foliated, lamellar, fibrous, or massive
Crystalline structure	Lamellar, brucite sheet between two silica sheets, forming talc layers superimposed indefinitely. All layers are electrically neutral and are held together by van der Waals forces

Added from (7,160,161,4)

WCD 001245

WCD 001246

TALC FIRST DRAFT
TABLE XII-2

SELECTED OCCUPATIONAL GROUPS
POTENTIALLY EXPOSED TO TALC*

Ceramics makers	Pottery makers
Carpet polishing workers	Printing ink makers
Cosmetic workers	Roofers
Insecticide workers	Roofing material makers
Leather treatment workers	Rubber cable coaters
Nurses	Rubber tire makers
Paint makers	Talc millers
Paper makers	Talc miners
Physicians	Talcum powder makers
Plastics makers	Textile makers

*Adapted from [162, 7, 203]

TABLE XII-3

MINERAL COMPOSITION (%) OF SAMPLES FROM TALC DEPOSITS IN THE USE*
AVERAGE PERCENTAGE (RANGE IN PARENTHESIS)

State/ number of Samples	Antho-phyllite	Calcite	Chlo-rite	Dolo-mite	Kyanite	Magne-site	Mica	Quartz	Talc	Tremo-lite/ Acti-nolite	Other
Alabama 4	0	0	5.2 (0-15)	0	<1 (0-1)	<1 (0-1)	0	<1 (.5-1)	91.9 (82-99)	0	1 Graphite <1 Hydroxy-apatite
Arkansas 1	0	2	8-10	10-20	0	15-25	0	2.4	33-57	0	5 Ankerite
California/4	0	5 (1-15)	<1 (0-5)	3 (0-15)	<1 (0-2)	0	<1 (0-3)	1.3 (0-2.7)	88 (52-96)	2 (0-10)	1-5 Feldspar 2 Rutile
Georgia/ 9	<1 (0-12)	2 (0-5)	15 (5-50)	3 (1-10)	2 (0-15)	1 (0-10)	5 (0-15)	2.3 (1.4-9)	50 (25-84)	5.5 (4-8)	<.5 Hema-tite .2-1 Magne-tite
Montana/ 7	0	<1 (0-1)	<1 (0-2)	2 (0-5)	<1 (0-1)	0	0 (.2-1.5)	<1	95 (95-98)	0	<.5 Hema-tite
New York/ 15	9 (4.5-13)	<1 (0-1)	0	<1 (0-1)	10 (1-20)	0	<1 (0-3)	1.0 (.2-3.5)	40 (19-73)	40 (13.5-49)	
North Ca-rolina/3	0	0	6 (1-20)	3	0 (2-5)	0	0	<1 (0-.5)	90 (75-97.5)	<1 (0-.5)	<.5 Hydroxy-apatite
Texas/ 19	0	<1 (0-2)	<1 (0-5)	5 (0-20)	<1 (0-1)	<1 (0-2)	<1 (0-5)	<1 (1.1-12)	85 (56-95)	<1 (0-2.5)	2 Antigorite 5 Forsterite 1 Graphite <1 Magnetite
Vermont/ 12	0	<1 (0-1)	3 (1-5)	10 (1-20)	0	30 (1-50)	<1 (0-1)	<1 (0-.5)	30 (4-98)	0	<1 Coal 5 Magnetite

WCD 001247

SRI International

Mr. Haynes
3-19-79

TALC

March 1979

By: Center for Occupational and Environmental
Safety and Health

Prepared for:

Division of Criteria Documentation and Standards Development
National Institute for Occupational Safety and Health

SRI Project No. 6455

SRI International
1611 N. Kent Street
Arlington, Virginia 22209

WCD 001248

PREFACE

The Occupational Safety and Health Act of 1970 emphasizes the need for standards to protect the health and provide for the safety of workers occupationally exposed to an ever-increasing number of potential hazards. The National Institute for Occupational Safety and Health (NIOSH) evaluates all available research data and criteria and recommends standards for occupational exposure. The Secretary of Labor will weigh these recommendations along with other considerations, such as feasibility and means of implementation, in promulgating regulatory standards.

NIOSH will periodically review the recommended standard to ensure continuing protection of workers and will make successive reports as new research and epidemiologic studies are completed and as sampling and analytical methods are developed.

The contributions to this document on talc by NIOSH staff, other Federal agencies or departments, the review consultants, the reviewers selected by the Society for Occupational and Environmental Health and the American Medical Association, and Robert B. O'Connor, M.D., NIOSH consultant in occupational medicine, are gratefully acknowledged.

The views and conclusions expressed in this document, together with the recommendations for a standard, are those of NIOSH. They are not necessarily those of the consultants, the reviewers selected by professional societies, or other Federal agencies. However, all comments, whether or not incorporated, were considered carefully and were sent with the criteria document to the Occupational Safety and Health Administration for consideration in setting the standard. The review consultants and the Federal agencies which received the document for review appear on pages v and vi.

Anthony Robbins, M.D.
Director, National Institute
for Occupational Safety and Health

WCD 001249

The Division of Criteria Documentation and Standards Development, National Institute for Occupational Safety and Health, had primary responsibility for the development of the criteria and recommended standard for talc. Anthony Romero of this Division served as criteria manager in completing the document. SRI International developed the basic information for consideration by NIOSH staff and consultants under contract 210-77-0015.

The Division review of this document was provided by Jon R. Bay, Ph.D. (Chairman), Richard A. Madsen, Ph.D., J. Henry Wills, Ph.D., and Roy Fleming (Division of Criteria Documentation and Standards Development); Jacqueline Nemits (NIOSH Region II Office); Donald D. Dollberg (Division of Physical Science and Engineering); Alice Crisp and John Gamble, Ph.D. (Division of Respiratory Disease Studies); Sherry Soloven (Division of Surveillance Hazard Evaluation, Field Studies); David N. Groth M.D., (Division of Biomedical and Behavioral Science); Loren L. Hatch, D.D., (Division of Technical Services); and John Decent.

WCD 001250

76 Bernard Grabois
79 Lake Hiawatha, New Jersey 07034

81 Dr. G. M. Lord
82 Johnson and Johnson
83 Research Foundation
84 New Brunswick, New Jersey 08903

86 Dr. John M. Peters
87 Harvard School of Public Health
88 Boston, Massachusetts 02115

WCD 001251

Department of Defense
Office of Deputy Assistant Secretary for
Energy, Environmental and Safety

Department of the Army
Army Environmental Hygiene Agency

Department of the Navy
Navy Environmental Health Center

Department of the Air Force
Office of the Surgeon General

Department of Health, Education, and Welfare
Food and Drug Administration
National Institutes of Health
National Cancer Institute
National Heart, Lung, and Blood Institute
National Institute of Environmental Health Sciences

Department of the Interior
Bureau of Mines

Department of Labor
Mine Safety and Health Administration
Occupational Safety and Health Administration

WCD 001252

CONTENTS

		Page
PREFACE		iii
REVIEW CONSULTANTS		v
FEDERAL AGENCIES		vi
I.	RECOMMENDATIONS FOR A TALC STANDARD	1
	Section 1 - Environmental (Workplace Air)	2
	Section 2 - Medical	3
	Section 3 - Labeling and Posting	5
	Section 4 - Personal Protective Clothing and Equipment	7
	Section 5 - Informing Employees of Hazards from Talc	9
	Section 6 - Work Practices	10
	Section 7 - Sanitation	12
	Section 8 - Monitoring and Recordkeeping Requirements	13
II.	INTRODUCTION	16
III.	BIOLOGIC EFFECTS OF EXPOSURE	19
	Extent of Exposure	20
	Historical Reports	31
	Effects on Humans	34
	Epidemiologic Studies	54
	Animal Toxicity	78
	Correlation of Exposure and Effect	92
	Carcinogenicity, Mutagenicity, Teratogenicity, and Effects on Reproduction	99
	Summary of Tables of Exposure and Effect	100
IV.	ENVIRONMENTAL AND ENGINEERING CONTROLS	104
	Dust Measurement	104
	Dust Analysis and Fiber Count	108
	Environmental Concentrations	116
	Engineering Controls	120
V.	WORK PRACTICES	127
VI.	DEVELOPMENT OF STANDARD	133
	Basis for Previous Standards	133
	Basis for the Recommended Standard	137

WCD 001253

CONTENTS (CONTINUED)

VII. RESEARCH NEEDS

VIII. REFERENCES

IX. APPENDIX I - Sampling and Analytical Method for Talc (Respirable Dust)

X. APPENDIX II - Sampling and Analytical Method for Asbestos Fibers Associated With Talc Dust in Air

XI. TABLE AND FIGURE

WCD 001254

Page

145

148

172

177

186

I. RECOMMENDATIONS FOR A TALC STANDARD

NIOSH recommends that occupational exposure to talc be controlled by adherence to the following sections. The standard is designed to protect the health and provide for the safety of employees for up to a 10-hour workshift, 40-hour workweek, over a working lifetime. Compliance with all sections of the standard should prevent adverse effects of talc on the health of employees and provide for their safety. Sufficient technology exists to permit compliance with the recommended standard. The environmental (workplace air) concentration is measurable by techniques that are valid, reproducible, and available to industry and government agencies. The employer should regard the recommended environmental limit as the upper boundary for exposure and make every effort to keep the exposure as low as is feasible. The criteria and recommended standard will be reviewed and revised as necessary.

The term "pure talc" refers to hydrous magnesium silicate ($Mg_3Si_4O_{10}(OH)_2$). Pure talc is a natural mineral with a crystalline structure consisting of a brucite sheet ($Mg(OH)_2$) sandwiched between two silica sheets and possesses such physical characteristics as softness, slipperiness, and hydrophobicity. In the recommended standard the term "talc" will refer to a mixture of pure talc and other minerals commonly found with it, including the microscopic nonfibrous forms of tremolite, actinolite, and anthophyllite. Commercial talcs do not necessarily conform to this definition; therefore subsequent chapters of this document may use the word talc to refer to minerals containing microscopic fibrous forms of tremolite, anthophyllite, actinolite and other asbestos minerals. The recommended standard in the

WCD 001255

following sections is for control of exposure to respirable airborne talc dust containing <50 (ug/cu m of free silica and <0.1 fibers/cc of asbestos minerals.

The recommended environmental limit is based on data indicating that talc may cause adverse respiratory effects and therefore, this limit should protect against the development of such effects. Exposure to talc may occur during the mining, milling, processing, distribution, storage, and use of talc. "Occupational exposure" to talc is defined as exposure to respirable airborne talc at a concentration above the action level. The "action level" is defined as a concentration in the air of the workplace at or above one-half the recommended environmental limit (see Section 1). Exposure to talc at lower concentrations requires adherence to the following sections 2, 3(a and b), 4, 5, 6, 7, and 8(a and c).

Talc is sometimes found mixed with free silica and asbestos minerals such as chrysotile and the microscopic fibrous forms of tremolite, anthophyllite, and actinolite. When this is the case, the employer should also comply with the proposed standard recommended by NIOSH for free silica and asbestos. These recommended standards can be found in the NIOSH criteria documents for occupational exposure to crystalline silica and to asbestos and in the revised recommended asbestos standard. If exposure to other materials also occurs, provisions of any applicable standards for the other materials shall also be followed.

Section 1 - Environmental (Workplace Air)

(a) Concentration

WCD 001256

Occupational exposure to talc shall be controlled so that employees are not exposed to mass respirable dust at a concentration >1.5 mg/cu m of air determined as a time-weighted average (TWA) concentration for up to a 10-hour workshift in a 40-hour workweek. This concentration may not be safe for talc workers who smoke.

Current specification recommends 1.3 mg/cu m (1)

(b) Sampling and Analysis

Environmental samples shall be collected and analyzed as described in Appendices I and II or by any method at least equivalent in accuracy, precision, and sensitivity.

Section 2 - Medical

Medical surveillance shall be made available as outlined below to all employees occupationally exposed to talc. The employer shall provide information to the physician performing, or responsible for, the medical surveillance program such as: the requirements of the applicable standard, an estimate of the employee's potential exposure to talc, including any available workplace sampling results, and a description of any protective devices or equipment the employee may be required to use.

(a) Preplacement or initial examinations shall include at least:

(1) Comprehensive medical histories, both personal and familial, with special emphasis directed toward identifying previous, existing, or developing disorders of the heart, lungs, and skin, comprehensive work histories to determine previous occupational exposure to potential respiratory irritants, including exposure to especially durable particulates and pulmonary carcinogens, and smoking histories;

WCD 001257

(2) Physical examination giving particular attention to the heart, lungs, and skin;

(3) Specific clinical tests, including at least a 35- x 42-cm posteroanterior and lateral chest X-ray film, and pulmonary function tests including forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV 1);

(4) An evaluation of the employee's ability to use positive and negative pressure respirators based on clinical and laboratory assessment of the employee's respiratory reserve including the results of the tests called for in (a)(1)(2) and (3).

(b) Periodic examinations shall be made available at least annually. These examinations shall include at least:

(1) Interim medical and work histories;

(2) Physical examination and clinical tests as outlined in (a)(2) and (a)(3) of this section except that X-ray film examination for workers occupationally exposed at average concentrations above the action level but below the TWA concentration need only be made available every 3 years for the first 9 years of employment and then biennually thereafter; annual examinations shall be made if in the physician's judgment it is needed.

(c) During examinations, applicants or employees found to have symptoms or medical conditions that might be aggravated directly or indirectly by exposure to talc shall be counseled on the increased risk of impairment of their health from working with this substance. Applicants or employees shall also be counseled on the possible increased risk of pulmonary injury from smoking during talc exposure.

WCD 001258

(d) Following completion of the examination, the physician shall give to the employer a written statement specifying any condition or abnormality found that would increase the risk to the employee's health by exposure to talc, and any limitations that should be placed on the employees' exposure.

(d) Pertinent medical records, correlated with environmental records and clinical data, shall be maintained for all employees occupationally exposed to talc. Such records shall be kept for at least 30 years after employment has ended. These records shall be made available to the designated medical representatives of the Secretary of Health, Education, and Welfare, of the Secretary of Labor, of the employer, and subsequent employer, and of the employee or former employee.

Section 3 -- Labeling and Posting

Employers shall be responsible for ensuring that containers and areas in which talc is present within the plant are labeled and posted, respectively. Labels and warning signs shall identify the substance present and describe the principal hazards that may arise from exposure. This information shall also state the most important precautions needed to safeguard health and safety. They shall also outline the important first aid procedures in case of intoxication or local contamination by talc. Such labels and warning signs shall be printed both in English and in the predominant language of non-English-reading workers. Workers unable to read the labels and posted signs provided shall be informed verbally in a language that they understand about hazardous areas and of the instructions printed on the labels and signs.

(a) Labeling

WCD 001259

Shipping and storage containers of talc shall bear labels describing the tradename, major ingredients, chemical name, and information on the possible adverse effects on human health as follows.

TALC

MAY CAUSE ADVERSE RESPIRATORY EFFECTS

Use only with adequate ventilation.
Avoid contact with eyes or open skin wounds.
Consult a physician if breathing becomes difficult.

(b) Posting

(1) The following warning sign shall be posted in readily visible locations at or near all entrances to areas where occupational exposure to talc may occur.

TALC

MAY CAUSE ADVERSE RESPIRATORY EFFECTS

Use only with adequate ventilation.
Avoid contact with eyes or open skin wounds.

(2) If respirators are required for protection in accordance with Section 4, the following statement shall be added to the sign required in Section 3(b).

RESPIRATORY PROTECTION REQUIRED IN THIS AREA

feel unnecessary

This study would indicate that load + cough limit are lower for Talc

WCD 001260

240 Section 4 - Personal Protective Clothing and Equipment

243 Engineering controls shall be used when needed to keep the concentration
244 of respirable airborne talc at or below the recommended environmental limit
246 specified in Section (1a).

249 (a) Respiratory Protection

252 (1) The use of respirators to comply with the permissible exposure
253 limit is permitted during installation and testing of engineering controls,
254 during the time necessary to install or test the required engineering
256 controls, during performance of nonroutine maintenance or repair, and during
257 emergencies.

259 (2) When a respirator is permitted or required it shall be selected
260 and used in accordance with the following requirements:

263 (A) To determine the type of respirator to be used, the
264 employer shall measure the concentration of respirable airborne talc in the
265 workplace initially and thereafter whenever control, process, operation, or
267 other changes occur that are likely to change the concentration of respirable
267 airborne talc.

270 (B) The respirator shall be selected in accordance with the
271 specifications in Table 1-1 and shall be those approved by NIOSH or the Mine
272 Safety and Health Administration (MSHA) as specified in 30 CFR 11.

275 (C) The employer shall establish and enforce a respiratory
276 protection program meeting the requirements of 29 CFR 1910.134 or 30 CFR 55,
277 56, 57, 5-5, whichever is applicable, and shall ensure that employees use the
278 required respiratory protective equipment.

WCD 001261

TABLE I-1

RESPIRATOR SELECTION GUIDE FOR TALC

Respirable Airborne Dust Concentration	Respirator Type Approved under Provision of 30 CFR 11
≤7.5 mg/cu m	Single use or quarter-mask dust respirator
≤15 mg/cu m	(1) Half-mask dust respirator (2) Supplied-air respirator with half-mask facepiece operated in demand mode with belt mounted demand regulator
≤75 mg/cu m	(1) Full facepiece high efficiency dust respirator (2) Full facepiece supplied-air respirator operated in demand mode with belt mounted demand regulator or self-contained breathing apparatus with full facepiece operated in demand mode
≤1,500 mg/cu m	(1) Powered air purifying respirator with a full facepiece and high efficiency filter (2) Supplied-air respirator with half-mask or full facepiece operated in pressure-demand mode or supplied-air respirator with half-mask, full facepiece, hood, or helmet operated in continuous-flow mode
>1,500 mg/cu m or entry into areas of unknown concentrations	(1) Self-contained breathing apparatus with full facepiece operated in pressure-demand or other positive pressure mode (2) Type C combination supplied-air respirator with full facepiece operated in pressure-demand mode and with auxiliary self-contained air supply



(D) Respirators specified for use in higher concentrations of talc may be used in atmospheres with lower concentrations.

(E) The employer shall ensure that respirators are adequately cleaned, maintained, and stored in a dust free condition. Employees shall be properly instructed and drilled at least annually in the proper use, fit, and testing for leakage of respirators assigned to them.

(F) Respirators shall be kept in locations easily accessible to employees.

(b) Protective Clothing

To prevent contamination of open wounds by talc the employer shall advise employees to cover such wounds, unless medically contradicted, with bandages, dressings, or other appropriate devices or work clothing, gloves or finger cots, depending on the exact location of the wound.

(c) The employer shall provide safety goggles for any employee experiencing eye irritation who is occupationally exposed to talc.

Section 5 - Informing Employees of Hazards from Talc

(a) Initial Education Program

In addition to the medical counseling required in Section 2(c), each employee assigned to work in an area where occupational exposure to talc may occur shall be informed verbally and in writing, by personnel qualified by training or experience, of the hazards and relevant signs and symptoms of exposure to talc. Workers shall be advised that exposure to talc may cause adverse respiratory effects and that exposure to talc and smoking may produce synergistic effects. The instructional program shall include a description of

WCD 001263

the medical surveillance procedures and of the advantages to the employee of participating in this program.

The employer shall also ensure that each employee is informed of the proper health and safety precautions for the production, processing, handling, use, and storage of talc. Employees shall also be instructed on their responsibilities for following proper work practices and sanitation procedures to help protect the health and provide for the safety of themselves and of fellow employees.

(b) Continuing Education Program

The employer shall institute a continuing education program, conducted by persons qualified by experience or training, to ensure that all employees have current knowledge of job hazards, proper maintenance and cleanup methods, and proper respirator usage. Employees shall be provided with up-to-date information whenever there is a process change.

Section 6 - Work Practices

(a) Control of Respirable Airborne Talc

Engineering controls, such as process enclosure and local exhaust ventilation, shall be used when needed to keep exposures to respirable airborne talc dust at or below the recommended environmental limit. Ventilation systems shall be designed to prevent the accumulation or recirculation of talc in the workplace environment and to effectively remove it from the breathing zones of employees. In addition to effective local exhaust ventilation, maintenance of a slight negative pressure in all enclosed systems that handle dry talc may be needed so that if a leak develops, talc

WCD 001264

will be be contained within the system. Exhaust ventilation systems discharging to the outside air shall conform to applicable local, state, and Federal air pollution regulations. Contaminated exhaust air shall not be recirculated into the workplace. Ventilation systems should be inspected annually and shall receive regular preventive maintenance and cleaning to ensure their continuing effectiveness and maintenance of design airflows. Airflow indicators should be used for continuous monitoring of the airflow. Records indicating a change in airflow measurements and corrective measures taken shall be kept together with environmental monitoring records.

(b) Control of Spills and Leaks

The employer shall ensure that only personnel properly trained in the emergency procedures and adequately protected against the attendant hazards shall be responsible for shutting off sources of talc, cleaning up spills, and repairing leaks. Dry sweeping shall be prohibited; cleanups shall be performed by vacuuming. In unusual circumstances such as spills, large amounts of talc may be removed by shoveling, and care shall be taken to create as little airborne dust as possible. Such cleanups shall be followed by vacuuming to remove any residue from shoveling. Pressurized gas shall not be used for clean up.

(c) Handling and Storage

Direct contact of open wounds with talc should be avoided. Care should be exercised in handling talc to minimize spills and dispersal of talc dust in the air. Talc should be stored in tight containers.

(d) Waste Disposal

Waste material contaminated with talc shall be disposed of in a manner

WCD 001265

that does not expose employees at concentrations above the recommended environmental limit. Disposal methods must conform to applicable local, state, and Federal regulations and shall not constitute a hazard to the surrounding population or environment.

(e) Confined Spaces

(1) Entry into confined spaces, such as tanks, dust collectors, process vessels, and tunnels, shall be controlled by a permit system. Permits signed by an authorized representative of the employer shall certify that preparation of the confined space, precautionary measures, and personal protective equipment are adequate and that prescribed procedures will be followed.

(2) Any employee entering confined spaces where the concentration of respirable talc may exceed the recommended environmental limit listed in Section (a) or where oxygen is deficient shall wear appropriate respiratory protection. The two workers shall be in constant communication by some appropriate means and shall be under the surveillance of a third person equipped to take action to rescue them if necessary.

Section 7 - Sanitation

Nondusty areas should be provided for eating and drinking. Grossly dusty clothing shall not be worn or carried home. Dust shall be removed from clothing by vacuuming rather than by pressurized gas.

The employer shall provide change rooms and separate storage facilities for street clothes and for work clothing and equipment. The change rooms shall be in a nonexposure area.

WCD 001266

Section E - Monitoring and Recordkeeping Requirements

(a) Bulk Sample Analysis

At least monthly, each producer of talc shall analyze of all talcs produced to ascertain free silica content and the presence or absence of minerals classified as asbestos. The composite bulk samples for these determinations shall be representative of at least 1 week's production of talc. Free silica determinations shall be quantified by X-ray diffraction. Asbestos determination shall be quantified using the electron microscopic method described in Appendix II. If asbestos is detected, environmental monitoring shall be conducted according to the procedure outlined in Appendix II.

In the workplace, all talc products shall be labeled as to free silica content and the presence or absence of asbestos as determined by electron microscopy.

(b) Industrial Hygiene Surveys

Each employer who processes or uses talc shall determine by an industrial hygiene survey whether occupational exposure has occurred or is likely to occur. Surveys shall be repeated at least annually and within 30 days of any process or other change. Records of these surveys, including the basis for any conclusion that the concentrations of talc do not exceed the recommended environmental limit listed in Section (a), shall be retained for at least 30 years after the employee's last exposure to talc.

(c) Personal Monitoring

If there is occupational exposure to talc, a program of personal

use CTFA method J-4-1

WCD 001267

monitoring shall be instituted to measure or permit calculation of the exposures of all employees to respirable dust.

(1) Each operation in each work area shall be sampled at least annually.

(2) In all personal monitoring, samples representative of the respirable dust in the breathing zones of the employees shall be collected.

(3) For each determination, a sufficient number of samples shall be taken to characterize the employees' exposures during each workshift. Variations in work and production schedules and in employees' locations and job functions shall be considered in choosing sampling times, locations, and frequencies.

(4) If an employee is found to be exposed to respirable talc dust in excess of the recommended environmental limit listed in Section 11(a), control measures shall be initiated promptly, and the employee shall be notified of the extent of the exposure and of the control measures being implemented. When the control measures have effectively reduced the employee's exposure to or below the recommended environmental limit confirmed by two consecutive determinations at least 1 week apart, routine monitoring may then be resumed.

(c) Recordkeeping

Records of workplace environmental monitoring shall be kept for at least 30 years after the employee's last exposure to talc. These records shall include the dates and times of measurements, job function and location of the employee within the worksite, methods of sampling and analysis used, types of respiratory protection in use at the time of sampling, TWA concentrations found, and identification of the exposed employees. Employees shall be able

WCD 001268

to obtain information on their own workplace environmental exposures.

Copies of records of environmental exposures applicable to an employee shall be included in medical records of environmental monitoring. The records shall be made available to designated representatives of the Secretary of Labor, of the Secretary of Health, Education, and Welfare, of the employer, and of the employee or former employee.

WCD 001269

WCD 001270

II. INTRODUCTION

This report presents the criteria and the recommended standard based thereon that were prepared to meet the need for preventing impairment of health from workplace exposure to talc. The criteria document fulfills the responsibility of the Secretary of Health, Education, and Welfare under Section 20(a)(3) of the Occupational Safety and Health Act of 1970 to "develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels...at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience" and under section 101(a)(6)(B) of the Federal Mine Safety and Health Act of 1977, to "submit to the Secretary of Labor all pertinent criteria regarding any such substances determined to be toxic or any such harmful agent as such criteria are developed."

After reviewing data and consulting with others, NIOSH formalized a system for the development of criteria on which standards can be established to protect the health and provide for the safety of employees exposed to hazardous chemical and physical agents. Criteria for a recommended standard should enable management and labor to develop better engineering controls resulting in more healthful work environments, and simply complying with the recommended standard should not be regarded as the final goal.

These criteria for a recommended standard for talc are part of a continuing series of documents published by NIOSH. The recommended standard applies only to workplace exposure to talc generated by the processing, handling, use, or storage of talc. The standard is not designed for the

population-at-large, and any extrapolation beyond workplace exposure is not
577 warranted. The standard is intended to: (1) protect against possible adverse
579 health effects, such as pulmonary lesions, cardiovascular disease, and
580 nonpulmonary granulomas, associated with exposure to talc, (2) reduce eye and
582 respiratory tract irritation due to exposure to talc, (3) reduce the risk of
583 the development of cancer from exposure to asbestos contaminants of talc, (4)
585 be measurable by techniques that are valid, reproducible, and available to
587 industry and government agencies, and (5) be attainable with existing
588 technology.

590 Talc is marketed in powder form, and varies in particle size from very
591 coarse to extremely fine. It is used in a variety of products including
592 paint, ceramics, paper, rubber, and plastics as an extender, filler, or
593 surface agent. In addition, talc is widely used in cosmetic products.
594 Occupational exposure to talc dust occurs during the mining, milling
595 (processing), handling, distributing, storage, or use of talc.

598 The available evidence indicates that workers occupationally exposed to
599 talc may develop pulmonary lesions and nonpulmonary granulomas. More data are
600 needed concerning the effects of relatively pure talc and talc found mixed
601 with its associated minerals on the pulmonary and other important physiologic
602 systems, such as the gastrointestinal and cardiovascular systems. Such
603 studies should also examine the clearance of talc administered through the
604 oral and inhalation routes. There is also a need for further epidemiologic
605 evaluation of the consequences of occupational exposure at low concentrations
606 of talc as well as a need for additional animal studies of the carcinogenic
607 potential of both relatively pure talc and the more commonly encountered types

WCD 001271

of talc mixtures. Further research should also determine possible synergistic effects produced by talc and minerals found in association with it - particularly chlorite, dolomite, magnesite, and the trace metals. A more complete discussion of these needs is presented in Chapter VII - Research Needs.

WCD 001272

III. BIOLOGIC EFFECTS OF EXPOSURE

Pure mineral talc is a hydrous magnesium silicate with the formula $Mg_3Si_4O_{10}(OH)_2$ and a theoretical composition of 31.7% MgO, 63.5% SiO_2, and 4.8% H_2O [1]. Deposits of talc rarely consist of the pure mineral; the talc is usually mixed with minerals such as chlorite, magnesite, dolomite, mica, antigorite, lizardite, chrysotile, microscopic nonfibrous and fibrous forms of tremolite, anthophyllite, actinolite, and varying amounts of trace metals such as iron, nickel, cobalt, chromium, and manganese. Commercially, the term talc refers to a mineral mixture having certain physical properties such as softness, slipperiness and hydrophobicity [1]. Usually, such mineral mixtures contain varying amounts of pure talc.

The talc crystal is lamellar and consists of a brucite sheet ($Mg(OH)_2$) sandwiched between two silica sheets, forming layers that are indefinitely superimposed [1]. The adjacent layers are held together by van der Waal's forces that are sufficiently weak to allow the layers to slide across one another readily, thus giving talc its slippery property. Pure talc only rarely occurs in a natural fibrous form, is inert in most chemical reagents, but is soluble in hot concentrated phosphoric acid [2]. The chemical, physical, and mineralogic properties of talc are summarized in Table III-1.

Talc deposits are primarily formed by two complex geologic processes [3,4]. They may evolve via hydrothermal alteration of magnesium- and silica-rich ultramafic rocks under low to moderate temperatures and pressures, and they may also be formed from thermal metamorphosis of a carbonate rock such as dolomite, $CaMg(CO_3)_2$, with the introduction of silica.

WCD 001273

Anthophyllite, $(FeMg)_7Si_8O_{22}(OH)_2$, chrysotile, $Mg_3Si_2O_5(OH)_4$, tremolite, $Ca_2Mg_5Si_8O_{22}(OH)_2$, actinolite, $Ca_2(Mg,Fe)_5Si_8O_{22}(OH)_2$, and other minerals may also be formed during the evolution of talc [1]. Table III-1 lists other minerals that commonly occur in talc deposits. The minerals found within talc deposits may occur as macroscopic nodules, as microscopic intergrowths with talc, or even as discrete zones within or adjacent to talc [4]. Talc rock ranges in color from white to green and brown, depending on composition, but after being ground to powder, most talc is white [1].

TABLE III-1

MINERALS THAT COMMONLY OCCUR IN TALC DEPOSITS

Mineral Group	Phase	Formula Approximations
Carbonates	Calcite	$CaCO_3$
	Dolomite	$CaMg(CO_3)_2$
	Magnesite	$MgCO_3$
Amphiboles	Tremolite	$Ca_2Mg_5Si_8O_{22}(OH)_2$
	Anthophyllite	$(FeMg)_7Si_8O_{22}(OH)_2$
	Actinolite	$Ca_2(Mg,Fe)_5Si_8O_{22}(OH)_2$
Serpentine	Antigorite	$Mg_3Si_2O_5(OH)_4$
	Chrysotile (uncommon)	$Mg_3Si_2O_5(OH)_4$
	Lizardite (uncommon)	$Mg_3Si_2O_5(OH)_4$
Others	Quartz	SiO_2
	Mica (eg, phlogopite)	$K_2(MgFe)_6(SiAl_2O_{20})(OH)_4$
	Chlorite (eg, penninite)	$(MgAlFe)_{12}(SiAl)_8O_{20}(OH)_{16}$

Adapted from reference [4]

The associated minerals in talc modify its physical properties, such as slipperiness. The differences in physical properties of talc mixtures make a

WCD 001274

wide range of commercial applications possible. Talc of high purity (>90%
703 pure), for example, is desirable for cosmetic and pharmaceutical use whereas,
704 talc containing tremolite is ideal for ceramic applications [1]. Table III-2
705 shows the composition and principal uses of talc originating in various
706 states. NIOSH has also identified and measured the amounts of various
707 minerals and trace metals occurring in bulk talc samples from these states
708 [5]. A summary of the results of the analysis appear in Tables III-3 and III-
709 4.

710 Tremolite, actinolite, and anthophyllite are among the minerals that have
711 been found in some talc deposits in the United States [2,5]. These minerals
712 may occur geologically in forms that are fibrous upon gross observation, and
713 the United States Bureau of Mines has classified these forms as the
714 asbestiform varieties, referring to them as tremolite asbestos, actinolite
715 asbestos, and anthophyllite asbestos [2]. According to the Bureau of Mines,
716 rock consisting of these fibrous varieties is not common. Rock not appearing
717 fibrous upon gross observation has been termed simply tremolite, actinolite,
718 and anthophyllite.

WCD 001275

TABLE III-2

COMPOSITION OF TALC MINED IN THE UNITED STATES

State	Mineral Composition and Impurities	Commercial Use
Alabama	Principally talc with minor amount of chlorite, traces of magnesite and quartz	Rubber, paint, textiles, and cosmetics
Arkansas	Talc mixed with dolomite, magnesite, and chlorite, minor amounts of quartz and calcite	Rubber, insecticides, and well tile
California	Principally talc and tremolite with minor amounts of forsterite, serpentine, and carbonates; impurities are chlorite, quartz, chlorapite, pyrite, and iron oxide	Rubber, pottery, paint, ceramics, paper, textiles, steatite, and pharmaceuticals
Georgia	Talc with minor amounts of magnetite and carbonates impurities are pyrite, chlorite, quartz, feldspar, actinolite, and sericite	Crayons, paint, rubber, roofing, insecticides, lubricants, foundry facings, and cosmetics
Montana	Essentially talc with minor impurities such as chlorite, graphite, and dolomite	Cosmetics, steatite, paints, paper, and ceramics
New York	Proportion of tremolite, anthophyllite, talc, and serpentine varies widely, any may predominate, but tremolite rock is most common; impurities are quartz, carbonate, diopside, manganese, and iron oxides	Largely ceramics and paint, also rubber, plastics, insecticides, and foundry facings

WCD 001276

TABLE III-2 (CONTINUED)

COMPOSITION OF TALC MINED IN THE UNITED STATES

State	Mineral Composition and Impurities	Commercial Use
North Carolina	Principally talc; traces of chlorite, dolomite, quartz, and tremolite	Cosmetics, steatite, pharmaceuticals, crayons, rubber, and paint
Texas	Essentially talc; impurities are various amounts of quartz, carbonate, and organic material	Chiefly wall tile; also insecticides
Vermont	Essentially talc with minor amounts of magnesite, chlorite, and sulfides	Paper, rubber, textiles, cosmetics, paint, roofing, crayons, and foundry facings

Adapted from references [6,7,1,5]

WCD 001277

TABLE III-3

RANGE OF MINERAL COMPOSITION OF BULK SAMPLES FROM TALC DEPOSITS IN THE USA (PERCENTAGE)

State/ Number of Samples	Anthophyllite	Calcite	Chlorite	Dolomite	Magnesite	Quartz	Talc	Tremolite/ Actinolite (Fibrous) %	Other Minerals In Some Samples
Arkansas/1	0	2	5-10	10-20	15-25	2.4	33-55	0	5 Ankerite
California/ 13	0	.3-15	0-5	0-13	0	0-2.7	52-96	0-10 (0-50)	5 Feldspar 2 Lizardite 3 Mica
Georgia/9	0-12	0-5	3-50	1-10	0-10	.4-9	25-84	4-8 (<.01-10)	<0.5 Hematite 1 Magnetite 15 Lizardite 15 Mica
Montana/6	0	0-1	0-15	0-5	0	.2-1.5	82-99	0	<0.5 Hematite 1 Lizardite 1.5 Mica 1 Graphite <1 Hydroxyapatite
New York/15	4.5-23	0-1	0	0-1	0	.2-5.5	19-73	13.5-57 (<.01-25)	20 Lizardite 5 Mica
North Caroline/3	0	0	1-20	2-5	0	0-.5	75-97.5	0-.5	<0.5 Hydroxyapatite
Texas/19	0	0-5	0-8	10-20	0-5	1.1-12	54-95	0-2.5 (0-80)	2 Antigorite 5 Forsterite 1 Graphite <1 Magnetite 3 Lizardite 1 Mica
Vermont/12	0	0-1	1-6	0-20	1-50	0-.5	43-99	0	<1 Coal 5 Magnetite 1 Mica

Adapted from reference [51]; 9 samples contained <10% talc and were omitted from table.

WCD 001278

TABLE III-4

TRACE METAL COMPOSITION OF BULK SAMPLES FROM TALC DEPOSITS IN THE USA (ppm)[a]

State/ Number of Samples	Cd	Co	Cr	Fe	Mn	Ni	Zn
Arkansas/1	<2	<20	640	35,900	740	720	53
California/13	<2	<20	3-22	1,210-19,200	28-300	<20-30	7-36
Georgia/11	<2-40	<2-73	<30-1,900	28,600-79,400	79-1,400	<20-1,420	24-103
Montana/12	<2-<30	<2-<20	<1-<30	280-16,600	17-6,090	<20-20	<3-100
New York/4	<10	<30	<10	595-935	1,720-1,960	<50	15-62
North Carolina/4	<30	<20	<30-6,300	2,200-5,700	<20-700	<30-490	<30
Texas/17	<2-<30	<10	<1-36	365-6,110	7-364	<20	<1-<30
Vermont/3	<10	75-90	280-660	25,900-49,600	70-850	1,220-1,490	<20

[a] Adapted from reference [5]

Tremolite, actinolite, and anthophyllite are amphibole minerals, and along with amosite and crocidolite, are classified with the serpentine mineral chrysotile as "asbestos," according to OSHA's workplace exposure standard [8]. Exposure to asbestos has been associated with respiratory diseases such as asbestosis, mesothelioma, and lung cancer, and NIOSH has reviewed the literature regarding the associated health effects in the documents Criteria for a Recommended Standard...Occupational Exposure to Asbestos [9] and Revised Recommended Asbestos Standard [10].

NIOSH considers the OSHA Asbestos Standard applicable to a talc mineral

WCD 001279

containing the microscopic fibrous forms of the asbestos minerals.
907 Identification of asbestos for compliance purposes consists of the microscopic
908 examination of these minerals using a phase contrast microscope at 400-450
909 magnification and the identification of fibers of at least 5 (um in length,
911 with a length to diameter ratio of 3:1 or greater [10]. Although it is not the
912 purpose of this document to re-evaluate the literature concerning the health
913 effects of asbestos, literature on talc containing asbestos minerals has been
914 included for purposes of completeness. Because NIOSH has already recommended
915 a standard [10] for occupational exposure to asbestos that will control
917 exposure to talc mixed with asbestos minerals, this document will concern the
918 medical and biological consequences of occupational exposure to talc that does
919 not contain asbestos minerals.

922 Free silica has also been found in talc deposits [5]. The adverse health
923 effects of free silica, primarily silicosis, have been extensively documented
924 and are reviewed in the NIOSH criteria document on crystalline silica [11].
925 As with tremolite, actinolite, and anthophyllite, the literature concerning
927 talc containing significant levels of free silica (>1%) is included only for
928 purposes of completeness and is not used to develop the recommended talc
929 standard since the OSHA and MSHA standard for occupational exposure to silica
930 will apply to airborne talc containing levels of free silica >50 (ug/cu m
931 [11]. Literature concerning talc found mixed with other minerals, such as
932 chlorite, dolomite, calcite, and other minerals frequently encountered with
933 talc, is included and will be used for developing the talc standard since
935 these minerals commonly occur with talc. Also, since there is insufficient
936 information available to suggest that the potential adverse health effects

WCD 001280

caused by these minerals are sufficiently different to warrant the development of separate standards, the proposed talc standard will also apply to these talc mixtures.

For consistency within this document, all studies relating to talc reported to contain tremolite, actinolite, or anthophyllite will be considered to concern talc containing asbestos minerals. Although not all samples of these minerals are fibrous, none of the studies used to prepare this document have identified these minerals, as found in talc, to be completely nonfibrous. In this document NIOSH will use the term fibrous to refer to minerals that have been microscopically characterized to contain fibers >5 (u) in length, with a length to diameter ratio of 3:1 or greater.

Terms generally used in literature for describing mineral talc or its associated minerals are defined as follows:

Asbestiform - "a specific type of mineral fibrosity in which the fibers and fibrils possess tensile strength and flexibility" [2];

Asbestos - "(1) a collective mineralogical term encompassing the asbestiform variation of various minerals; (2) an industrial product obtained by mining and processing primarily asbestiform minerals" [2];

Asbestos fiber - for counting or compliance purposes, a particulate that has a physical dimension longer than 5 (u), with a length to diameter ratio of 3 to 1 or greater [12];

Asbestos minerals - chrysotile, crocidolite and the fibrous forms of tremolite, anthophyllite, and actinolite;

Cosmetic grade talc is a high grade talc intended to be marketed for cosmetic purposes. Cralley et al [13], in 1968, identified fibers in talc

WCD 001281

powders sold commercially, and Rohl et al [4] identified fibers as asbestos in
974 10 out of 21 randomly selected cosmetic talc products formulated before 1973.
976 Cosmetic talc is therefore considered to be of unknown composition, unless
977 otherwise stated.

979 Fibrous - the natural occurrence of a mineral in bundles of fibers,
980 resembling organic fibers in texture, from which the fibers can usually be
981 separated [2];

984 French chalk - a variety of soapstone or steatite [14];

987 Granular - the shape of crystals having approximately equal dimensions and
988 that are nonspherical [14];

990 Industrial or technical grade talc - a talc mixture consisting of varying
991 amounts of talc and associated minerals [15];

993 Mineral fiber - the smallest elongated crystalline unit that can be
994 separated from a bundle or appears to have grown individually in shape and
995 that resembles organic fibers [2];

997 Pharmaceutical grade talc - high grade talc processed for use in
998 pharmaceutical industries [16];

1000 Platy - "the shape of a crystal with one short dimension and two longer,
1001 approximately equal dimensions" [2];

1004 Soapstone - massive form of mineral talc [14];

1006 Many studies found in the available literature expressed workplace
1008 exposure concentrations in millions of particles per cubic foot (mppcf) as
1010 determined by counting methods. Recent studies [17,18] have reported results
1010 of parallel sampling for total dust counts in mppcf and mass respirable dust
1012 concentrations, determined by counting and gravimetric methods, respectively.

WCD 001282

There appears to be no specific correlation between mg/cu m and mppcf for the same exposure measurement [19,20]. Therefore, exposure concentrations in papers discussed in this document will be presented as reported by the investigators and no attempt will be made to standardize the values reported.

Extent of Exposure

Talc is used as an extender, filler, and versatile component in many industrial products. Approximately 70% of the talc produced is used in paint, ceramics, rubber, roofing materials, and paper. The rest of the talc (usually over 90% pure) is used in cosmetics, pharmaceutical products, agricultural chemicals, and in the food industry, where it is used for processed-meat dusting, candy molding, and polishing of peanuts and rice [15]. Talc is also used in chalks and crayons, insecticides, foundry facings, textiles, white shoe cleaners, pigments, dusting powders, soap fillers, and lubricants. In 1976, the total production of talc in the United States was approximately 1,200,000 tons. Other leading producing countries were Japan, 1,500,000 tons; USSR, 500,000 tons; People's Republic of China, 330,000 tons, and France 316,600 tons [21]. Production of talc minerals in the United States increased between 1953 and 1974 at an average rate of 5.4%, and the demand for talc is expected to increase through the year 2000 [16].

Geologic processes determine the composition of talc mixtures and, consequently, dictate to a large extent the properties and the end use of the talc (see Table III-2). Talc milling processes rarely alter the composition of the talc mixture that is mined but rather produce a talc product having desired physical properties, primarily dependent on particle size.

WCD 001283

Since talc is usually found mixed with other minerals or trace metals, workers in mining, milling, and end-user facilities are exposed to a mixture of mineral dusts rather than to pure mineral talc [22]. Worker exposure to talc dust occurs when talc is transferred, added to, or dusted on products, and during accidental rupture of bags or failure of engineering controls in milling plants during crushing, separation, bagging, and loading, and in end-user facilities [22].

NIOSH estimates that, in 1977, approximately 2 million workers were occupationally exposed to various forms of talc in mining, milling, and end-user facilities. MSHA estimates that approximately 1.1 million of these workers are exposed during mining and milling (S Hutchison, personal communication, February 1979). Selected occupations where workers are potentially exposed to talc are listed in Table III-5.

This document is concerned mainly with the health and safety of workers exposed to talc in mining, milling, and end-application operations. The engineering controls and work practices in these operations may be different, however. Those for the mining and milling processes will be discussed in a subsequent document on mining. Employees engaged in talc mining and milling operations will be covered by the safety procedures and health regulations promulgated and enforced by MSHA of the US Department of Labor.

WCD 001284

TABLE III-5

SELECTED OCCUPATIONS WITH POTENTIAL EXPOSURE TO TALC

Ceramics makers	Painters
Cereal polishing workers	Paint makers
Cosmetic workers	Paper makers
Chemical technicians	Pharmacists
Chemists	Physicians
Compositors and typesetters	Plastic makers
Cutting operative workers	Printing ink makers
Freight and material handlers	Roofers
Funeral directors	Roofing material makers
Hairdressers and cosmetologists	Rubber cable makers
Insecticide workers	Rubber tire makers
Job and die setters	Talc millers
Leather treatment workers	Talc miners
Mixing operative workers	Talcum powder makers
Nurses	Textile makers
Nursing aides, orderlies, and attendants	Vehicle washers and equipment cleaners
Other machine operators	

Adapted from reference [6]

Historical Reports

In 1898, Thorel [23] published the first description of talc pneumoconiosis (talcosis) in a 46-year-old woman who had been exposed to soapstone in a factory for a period that the author described as several

WCD 001285

years. At autopsy, Tharsi found talc dust in the walls of the alveoli and nodular lesions in the lung with macrophages, giant multinucleated cells, and granulation tissue.

An International Labor Organization publication reported a case of pneumoconiosis, described by Sand, in a woman who had worked several years in an atmosphere of talc dust [24]. Talc particles were found during autopsy through microscopic examination of the alveoli and the conjunctivae.

In 1931, Zanelli [25] reported the case of a 27-year-old woman who was exposed daily to large amounts of talc dust in a factory that produced rubber tires. After she had been exposed to the dust for 5 years, an X-ray film of the woman's lung showed reticulation and nodular shadows consistent with pneumoconiosis. She complained of digestive disturbances, a decrease in her sense of smell, redness of the conjunctivae and burning of the eyes. No data on the composition of the talc or of exposure concentration were provided in any of these early studies [23,24,25].

Conflicting accounts of the biologic hazards of exposure to talc came from early experiments with animals. In 1931, Haynes [26] published the results of an extensive study on a variety of dusts. He exposed 12 guinea pigs to a talc dust for 2 hours/day for 2 weeks. The author did not report the composition of the talc or data on exposure concentrations used. He found no pulmonary damage and noted brisk bronchial and lymphatic removal of the dust from the lungs. Based on these brief exposures, Haynes classified talc as nonharmful, since it had caused no permanent damage to the lungs.

Policard [27], in 1939, reported the results of a study of an unspecified number of rats exposed 3 hours/day for 12 days to a talc dust of unknown, but

WCD 001286

what the author considered to be high concentrations. The talc was identified as industrial foliated talc with particles measuring <5 fu/m (particle size not characterized). Policard observed upper respiratory tract irritation and marked, labored breathing, that he attributed to the high concentration of talc used. At necropsy, he saw dilatation of the bronchi, emphysema, and suppurative alveolitis. On microscopic examination of stained sections of lung, elimination through the lymphatic system did not appear to have been extensive and particles of talc were found to have been engulfed by alveolar macrophages without damaging these cells. Data presented in these papers [26,27] were insufficient to permit a determination of whether the differences in the responses observed were due to differences in the species of animals exposed, in the compositions of the talc used, or in the exposure conditions.

In 1933, Arlopet [28] called attention to the risk of granuloma formation induced by talcum powder from rubber gloves worn by surgeons. Patients who had had abdominal surgery were examined. In two instances, microscopic examination revealed particles of talc in giant cells in abdominal granulomas. In 1937, Fienberg [29] reported on five surgical cases in which particles of talc were discovered in nodular lesions with foreign body reaction at the sites of previous operations. He also produced similar lesions experimentally by injecting talc into mice intraperitoneally (ip).

Schulz and Williams [30], in 1962, were apparently the first to recognize that differences in the mineral composition and physical properties of talc might account for the different responses observed. After analyzing 51 commercial talcs, the authors picked seven with different ratios of silicate to carbonate and different amounts of tremolite and serpentine. These seven

WCD 001287

talcs were sterilized, and 200 mg of each as a 5% saline suspension was injected ip into a group of ten guinea pigs. At necropsy, microscopic examination of tissues sampled showed that talc particles were held in a local area by phagocytic cells of the macrophage and giant cell type. The authors reported that fibrosis occurred and was limited to the area in which the foreign material was stored and that the development of fibrosis was minimal compared with that produced by crystalline silica. The greatest degree of fibrosis was produced by 3% dusts which contained 62% tremolite, and 3% serpentine (type of serpentine identified was not given), 8% carbonate, and 4% other minerals, an early indication that talc containing asbestos may pose a greater hazard to health than talc free of asbestos.

Effects on Humans

Since adequate information concerning the composition of talc often has not been presented in the biological and medical literature, the relative magnitudes of the effects due to other minerals occurring with talc are difficult to assess. For purposes of comparison, the studies on the respiratory effects of talc on humans will be presented according to the effects of talc without asbestos minerals, talc with asbestos minerals, and talc of unknown composition. Other health effects will be presented under nonrespiratory health effects due to exposure to talc.

(a) Talc without asbestos minerals

Millman, in 1947, described a case of pneumoconiosis resulting from exposure to cosmetic talc [31]. At the time the worker was examined, the talcum powder consisted of talc mineral with small quantities of zinc

WCD 001288

stearate, cuecholin, chalk and coloring added during the manufacturing process. The author reported that optical microscopic examination of the powder revealed no sharp spicules such as those that have been reported in talc containing tremolite, and analysis for free silica revealed a concentration of <0.5%. Area sampling revealed that the concentration of dust in the general room where the worker was exposed was 15.9 mppcf and a concentration as high as 226 mppcf was reported during the process of filling the machine that mixed the talc with other ingredients.

The patient examined was a 35-year-old man, who had worked in the cosmetic talcum powder industry for 24 years [31]. He complained of occasional chest pain and general weakness. Breath sounds were normal and no heart abnormality was found on physical examinations. An X-ray film of the chest revealed nodular densities between 1 and 3 mm in size scattered throughout both lung fields and both hilar regions, and a thickened pleura between the upper and middle lobes of the right lung. Millman concluded that these findings were consistent with a diagnosis of pneumoconiosis and remarked that this was the first case, to his knowledge, of exposure to cosmetic talc to have caused a definite case of pneumoconiosis [31].

Fristedt et al [32], in 1968, described five cases of pneumoconiosis found in an unspecified number of workers at a rubber manufacturing plant in Sweden in 1966. The talc used at this plant was mostly granular and contained <1% quartz and no asbestos as determined by X-ray diffraction analysis. The five men in whom pneumoconiosis developed were 46-62 years old (average 57 years) and had 11-40 years (average 30.2 years) of workplace exposure to talc. Of the five, three worked in the department that manufactured inner tubes where

WCD 001289

the dust concentrations were 23-99 mppcf (average 58.5 mppcf) during 1967.
The remaining two workers were employed in the water hose department where the dust concentrations in 1967 were 10-121 mppcf (average 37 mppcf). Most of the dust particles in both departments were <5 fu/s in length, but the percentages of needle-shaped particles 5-20 fu/s in length and above 20 fu/s in length were 0-1.2% and 0.02-0.05%, respectively, in the inner tube department, and 0.7% and 0.03%, respectively, in the water hose department.

Of these persons employed in the inner tube department, two had mild talcosis without impairment of lung function, while the third had stage III pneumoconiosis with a slight reduction of lung function (the type of lung function test was not mentioned) [32]. The worker suffered from stage III pneumoconiosis and rheumatoid arthritis (Caplan's syndrome). The author observed that the development of pneumoconiosis is often faster in workers with chronic rheumatoid arthritis and may occur after a relatively short exposure duration. Stage I talcosis without impairment of lung function was diagnosed in one person who worked in the water hose department, while another worker in the same department, who also had had 9 years of exposure to quartz sand from working in an iron foundry, had mild talcosis or talcosilicosis. Examination of biopsy material from lymph nodes of the mediastinum of the workers revealed fibrosis and high (no values given) concentrations of talc, about 5% of the particles being birefringent crystals [32].

Fristedt et al [32] pointed out that the dust measurements did not reflect the actual exposure of the five workers but only what the situation was at the time of the measurements. They also pointed out that while the dust composition may have remained the same throughout the exposures, they raised

WCD 001290

the question of whether or not there had been periods when the talc material had been mined from actinolite-rich veins. The authors did state, however, that they believed the cases of pneumoconiosis reported here were caused by talc without asbestos or silica because the disease appeared to be relatively mild and had only occurred following many years of exposure. They characterized the pneumoconiosis as resembling a slowly progressing siliconis.

Scansetti et al [33], in 1983, reported the results of an examination of 72 workers exposed to talc at unknown concentrations in Italy during the processing of rubber. Although the composition of the talc mixture was not reported in this study except for the statement that it contained no free silica, it is assumed that the composition is the same as that reported by the other authors in a subsequent study [34]: that is, talc without asbestos minerals but with low levels if any of free silica.

Chest X-ray films were taken, medical histories were recorded, and pulmonary function measurements were performed on the population of workers [33]. The concentration of talc to which the workers were exposed was not stated and the average length of exposure was 7.1 years.

According to the authors, the pulmonary function measurements revealed no alterations worth mentioning either at rest or after stress [33]. Also, a low incidence of bronchitis (8%) and emphysema (5%) was found from physical examination and evaluation of reported symptoms. Chest X-ray films of 50% of the workers showed increased markings. The percentage of the 34 workers having abnormal X-ray film findings increased with the duration of exposure. The X-ray films of workers employed for <3 years showed mostly normal lung fields (79%), whereas 50% of the 10 employed for 4 to 6 years, and 86% of the

WCD 001291

28 employed for >6 years showed abnormal lung fields. The authors stated that the alterations in the X-ray films observed were of the type that remained unchanged even after prolonged periods of exposure and that no nodulations of the silicosis type were observed. They characterized the alterations seen as accumulation pneumoconiosis and stated that the alterations were limited to accentuation of the lung markings and did not affect either respiratory function or working capacity.

A subsequent study by Scansetti et al [35], in 1983, examined the X-ray films, pulmonary function measurements, and clinical signs of respiratory disease through a prospective study of a group of Italian talc miners. The initial group examined consisted of 235 workers who were exposed for an average duration of 4.9 years. Subsequent examinations were made after average exposures of 14.3, 16.5, and 19.5 years with 229, 55, and 22 workers, respectively.

Analysis of the data showed that the occurrence of emphysema increased with exposure duration (average of 19.5 years exposure) until 77% of the workers were diagnosed as having emphysema in the final follow-up [35]. The incidence of bronchitis peaked at the third follow-up (85%) and then declined to 54.5%. The authors also noted a gradual appearance of signs of right heart involvement such as pulmonary type P waves and right ventricular hypertrophy as detected through electrocardiographic studies. A gradual decrease was observed in the percentage of X-ray films diagnosed as normal until none of the 22 exposed for 19.5 years was so classified. Respiratory function measurements such as vital capacity and forced expiratory volume showed a progressive decrease both with increasing duration of exposure and with

WCD 001292

increasing severity of lesions seen in the X-ray files.

The authors [35] concluded that there was a good correlation between deterioration of respiratory function parameters and the evolution of the pneumoconiotic process, although a statistical analysis was not presented. The progression of the signs and symptoms of pneumoconiosis with increasing duration of talc exposure is documented in this study, although the influence of such factors as smoking and normal aging processes on the development of pneumoconiosis were not addressed.

(b) Talc with asbestos minerals

Many deposits of talc contain contaminants such as tremolite, actinolite, anthophyllite, and chrysotile. However, only the naturally fibrous forms of tremolite, actinolite, and anthophyllite are considered by mineralogists to be asbestos minerals [2]. The tremolite in most talc deposits exists as the grossly nonfibrous form however, microscopic fibers of tremolite and anthophyllite have been found in commercial talcs [19,18]. A number of reports have described the lungs and the pulmonary functions of workers exposed to these talc mixtures. Although these studies yield information concerning the pneumoconiotic disease process and help to relate intensity and duration of exposure to effects on the health of workers, it is impossible to separate the effects of asbestos and silica from those of talc or to accurately determine the magnitude of the effects caused by talc alone.

Dreessen [36] reported in 1938 the results of studies of 57 miners and millers exposed to talc that contained tremolite. Dust samples were taken with an impinger, and the average concentration at the drill face was 1,440 mppcf. Millers were exposed to talc dust at an average concentration of 52

WCD 001293

mppcf, whereas the ambient air contained 4 mppcf. The exposure durations varied from <5 years to >40 years and averaged about 10 years. The author noted that 65% of the particles of talc were <2 (um in diameter, and that none of the particles exceeded 6 (um in diameter. Although a complete chemical analysis of the talc was not presented, Dreessen reported finding no free silica in the form of quartz and stated that talc and tremolite occurred in about equal percentages, each composing about 45% of the mineral.

Examining X-ray films of the workers, Dreessen found that fibrosis was more extensive than usual but did not show definite stage I changes in 67% of the workers (36). However, 26% had stage I pneumoconiosis, 2% (one worker exposed for 40 years) had stage II pneumoconiosis, while only 5% had normal lungs. Dreessen described stage I pneumoconiosis as a "diffuse, fine, generalized fibrosis...chiefly confined to the lower two-thirds of the lung fields," and stated that it apparently caused little disability.

The fibrosis and pneumoconiosis appeared to be associated with increasing levels of exposure (36). Of 10 workers exposed at an average concentration of 1,440 mppcf, four workers had a diagnosis of fibrosis and six workers had pneumoconiosis. Ninety seven percent of 33 workers with an average exposure concentration of 52 mppcf had fibrosis (22) or pneumoconiosis (10). Of 14 workers with an average exposure concentration of 4 mppcf, 12 workers had fibrosis without observable pneumoconiosis. Although the author did not calculate average exposure durations for each exposure level group, 71% of the workers were reportedly exposed for <9 years.

In 1935, Dreessen and DallaValle (37) reported on two Georgia talc mills and mines and reported on 66 workers exposed to talc that contained tremolite.

WCD 001294

1445 Talc dust samples were taken with an impinger. The average exposure
1446 concentration for the miners was reported at 135 mppcf. In the mills,
1448 analysis of the dust samples indicated an average of 70% talc, 20% dolomite,
1449 and 10% tremolite. Only occasional fragments of free silica were found and
1451 these were too few to be considered significant by the authors. The median
1453 size of the particles found was 0.6 (u)m in diameter, and 95% of them were
1454 >0.5 (u)m in diameter, indicating a possible difference in particle size from
1455 the previous study [36]. X-ray film examinations showed that 6 of 13 (46%)
1457 miners exposed to talc dust at an average of 135 mppcf and 10 of 23 (48%) mill
1458 workers exposed at 300 mppcf or more had pneumoconiosis.

1461 The talc to which workers were exposed in this study [37] contained about
1462 22% as much tremolite as that involved in the earlier study by Dreessen [36].
1463 Dreessen and DallaValle [37] concluded that exposure at high concentrations of
1465 talc with low concentrations of tremolite was more hazardous to workers'
1466 health than exposure at low concentrations of talc containing more tremolite,
1467 based on the more frequent occurrence of severe pneumoconiosis in the second
1468 group studied. However, a comparison of the two studies [37,36] shows that
1469 although millers in the latter study [37] were, in fact, exposed to a greater
1470 concentration of talc (300 mppcf vs 52 mppcf), they were also exposed to a
1472 greater concentration of tremolite (30 mppcf vs 23 mppcf). Therefore, it may
1472 be unwarranted to assume that greater total dust exposure was the more
1474 important single factor in the increased incidence of pneumoconiosis seen in
1475 the second study.

1477 In X-ray film examinations, reported in 1963, of 221 male talc miners and
1478 millers in New York State exposed to talc that contained microscopic fibrous

WCD 001295

tremolite and 1% or less free silica. Siegel et al found 32 (14.5%)
individuals with evidence of marked pulmonary fibrosis [38]. The workers were
exposed to talc dust at concentrations of 6-5,000 mppcf in mining operations
and of 20-215 mppcf in milling operations. Other workers had mild or moderate
fibrosis, but no further information concerning them was supplied by the
author. In terms of employment duration, 6 of 8 workers (75%) employed for 30
years or more, 26 of 99 workers (26%) employed for 10-30 years, and 0 of 114
workers employed for <10 years showed evidence of marked fibrosis. The
fibrosis was reported to be disabling, with an X-ray film appearance of fine
and diffuse granulation or nodulation on a hazy background. Pleural plaques on
the surfaces were found in 14 of the 22: workers (64%).

A follow-up examination of this same population 10 months later, focusing on selected men who had fibrosis and who had been previously exposed only to talc containing microscopic fibrous tremolite, showed that 17 of 18 with advanced fibrosis were aged 40 years or older and all 18 had been exposed to talc for 10 or more years [38]. Of the 18 men with advanced fibrosis, 13 had 1 or more respiratory symptoms, 10 complained of labored breathing, 7 of chronic cough, and 3 of chest pain. Five men also complained of excessive fatigue. The author noted pleural calcifications and the similarity of this abnormality with that produced by asbestos.

In a study 14 years later, Kleinfeld et al [39] described the condition of the 32 men with marked fibrosis studied by Siegel et al in 1943 [38]. By this time, control measures had been instituted and dust concentrations in the work environment had been reduced to 3-6 mppcf in the mining operations and to 3-300 mppcf in the milling operations [39]. Nineteen of the 32 men had died, 4

WCD 001296

from respiratory failure associated with pneumoconiosis and 15 from causes reportedly unrelated to exposure to talc although one had mesothelioma of the pleura. Of the 13 survivors, 6 of whom were still employed, the outstanding clinical findings involved the pulmonary and cardiovascular systems and were manifested as labored breathing, coughing, basal rales, diminished chest expansion, and clubbing of fingers. X-ray film examinations showed a diffuse infiltration of the basal and midlung fields, occasional nodules, cor pulmonale, and emphysema. In addition, plaques were observed in the region of the diaphragm and pericardium and in parts of the lung fields.

Abnormal electrocardiograms including right and left ventricular hypertrophy, rhythm and T-wave alterations were observed in six men [39]. Kleinfeld et al noted that the abnormalities observed in this group of men suggested serious disorders of the pulmonary and cardiovascular systems. They noted that the disease appeared to have progressed in all workers although the course was slow. Kleinfeld et al did not report the smoking habits of the workers nor did they attempt to account for the normal effects of aging on the progression of the disease.

A number of other studies of the respiratory systems of talc milling workers have been reported by Kleinfeld et al [40,41,42,43]. The authors [41], in 1963, reported on six cases of talc-induced pneumoconiosis. The men (aged 42-67 years) had been exposed to a talc dust containing unspecified amounts of the microscopic fibrous forms of tremolite, anthophyllite, and approximately 5% free silica for an average duration of 29 years. Estimated talc dust exposure concentrations were 29-470 mppcf (average 221 mppcf)). The major clinical features were chronic productive cough, labored breathing, diminished

WCD 001297

breathing sounds, limited chest expansion, diffuse rales, and clubbing of fingers. Cor pulmonale was present in four patients. Changes observed in the lungs included diffuse fibrosis, granulomas, alveolar cell metaplasia, bronchiectasis, emphysema, silica-like nodules, and pleuritis. A pattern of endarteritis consisting of intimal hypertrophy and reduplication was common, and there were four cases of right ventricular hypertrophy. The authors stated that these changes were consistent with those seen in pulmonary hypertension.

Kleinfeld et al [42], also investigated the pulmonary functions of 20 talc workers who had developed talcosis as indicated by positive clinical and X-ray film findings. In this study, all workers had been exposed to dust containing talc, tremolite, anthophyllite, and free silica for 11-40 years (average 23 years) at concentrations exceeding 50 mppcf. The pulmonary function of these workers was affected, and the test results indicated restrictive or obstructive breathing disorders [42].

In a similar study [43] published in 1965, the authors examined 86 talc workers with different degrees of pulmonary fibrosis (indicated by X-ray film findings). These workers, 29-69 years old (mean 54.8 years), were exposed primarily to talc mixed with tremolite, anthophyllite, serpentine, and <5% free silica for 13-26 years at a TWA concentration of 68.9 mppcf. A number of these workers developed labored breathing and impaired ventilatory function and diffusion capacity.

In a matched control study reported in 1965 [40], Kleinfeld investigated pulmonary functions in 43 millers exposed for more than 10 years (average 19 years) to dust that contained talc, tremolite, anthophyllite, serpentine, and <5% free silica at a mean weighted concentration of 62.3 mppcf. These workers

WCD 001298

were 29-69 years old (mean 50.1 years). Forty-one workers of similar age range, 32-71 years (mean 48.0 years), and smoking habits but with no exposure to talc were used as controls.

The predominant clinical symptoms and signs observed in these talc workers were labored breathing (67.4%), cough (27.9%), lung crepitations (27.9%), and clubbing of fingers (18.6%) [40]. None of the controls had coughing or clubbing of fingers, and only 4.9% and 7.3% exhibited labored breathing and lung crepitations, respectively. The differences in the incidences of these symptoms among talc workers and among controls were statistically significant ($P<0.05$). No one in either group had electrocardiographic findings indicative of cor pulmonale.

Five pulmonary function tests performed were vital capacity, 1-second vital capacity (FVC 1), residual volume, total lung capacity, and single-breath pulmonary diffusion capacity for carbon monoxide [40]. Except for residual volume, the talc workers had lower mean values than the controls for each function. Mean values for vital capacity and total lung volume for the controls were generally about 100% of values predicted on the basis of regression equations whereas the talc workers had 79.7% and 84% of the predicted values, respectively ($P<0.01$, $P<0.05$). The FVC 1 measurements reported in mean percentage of vital capacity, were 71.8% for talc workers and 76.3% for controls. For the pulmonary diffusion capacity, the talc workers had a mean of 24.2 cc/mmHg/minute, and the controls had 27.3 cc/mmHg/minute.

X-ray film examinations revealed that 16 of the 43 talc workers had positive pulmonary infiltration, whereas none of the controls had such changes [40]. The authors further investigated the difference in clinical findings

WCD 001299

and pulmonary function changes between those exposed workers with and without pulmonary infiltration. The incidences of coughing, labored breathing, lung crepitation, and clubbing were significantly higher ($0.01<P<0.05$) in workers with pulmonary infiltration. However, only vital capacity and diffusion rate were significantly low ($0.01<P<0.05$) in those having pulmonary infiltration. The authors stated that there was no strong relationship between pulmonary function measurements and the clinical, X-ray film, and environmental findings for individuals within the group of talc workers studied.

These studies [40,42,43] included X-ray film findings indicative of pulmonary fibrosis, various decreased pulmonary function measurements, and an increased occurrence of clinical signs and symptoms of respiratory disease that developed after occupational exposure to talc containing tremolite and 5% or less free silica. The lack of strong correlation of pulmonary function measurements with abnormal clinical and X-ray film findings in individuals that Kleinfeld et al reported may arise from the human variability of the sample population with respect to these parameters.

Miller et al [44], in 1971, reported the case of a 62-year-old man who for 2 years cleaned ventilators that collected excess talc dust (predominantly pure talc with some traces of anthophyllite) in a factory that produced rubber condoms. Eleven years after leaving that job, he was admitted to a hospital complaining of increasingly labored breathing, wheezing, coughing, and expectoration [44]. Following hospitalization, progressive cor pulmonale developed and the patient died approximately 1 year later of cardiopulmonary insufficiency. Results from a open-chest lung biopsy performed after hospitalization indicated fibrosis of the lung parenchyma and granulomas

WCD 001300

composed of epithelioid and multinucleated giant cells surrounded by a thin layer of lymphocytes. The lung was emphysematous, with thin intraalveolar septa, and the pleura was thickened and fibrotic, with granulomas similar to those found in the pulmonary parenchyma. Talc particles could not be found by light microscopy, but were found in large amounts, after microincineration of the lung samples, by the use of X-ray diffraction, electron microscopy, and polarising microscopy.

(c) Talc of unknown composition

Studies have also been found that indicated adverse effects on the health of workers who had been exposed to talc of unknown mineral composition. The authors' descriptions in these studies do not preclude exposure to traces of asbestos with talc or other minerals commonly encountered with talc.

In 1955, Alivisatos et al [45] described an unusually rapid development of talcosis in eight workers who milled talc and packed talc powder into sacks. The talc used in these plants contained 48-52.2% silicate salts (calculated by the author as silicic acid) but no free silica. While the number of particles of some samples near the mills and transportation areas were described as "innumerable" (not measurable with available sampling equipment), the concentrations of most samples from various plant areas ranged between 11.6 and 60.8 mppcf and the diameters of 43-93% (average 70.5%) of the particles were 5 fibs or less.

Of the eight workers, aged 22-49 years (average 35 years), who developed talcosis, six had worked at their current jobs for 18-26 months, one for 40 months and another for 60 months [45]. The first signs and symptoms of talcosis, such as a productive cough, mucopurulent sputum, and labored

WCD 001301

breathing on exertion were found as early as 16 months after the worker began on the job. Casts of bronchioles composed of talc were found in the sputum of one worker. Some of these workers also suffered from general weakness and had lost weight as the disease progressed. Ten months after these examinations, one of the eight workers died of pulmonary failure.

Chest X-ray films of three of the remaining seven workers revealed stage III pneumoconiosis characterized by mottling and nodular shadows of "tumor-like" appearance in both lungs, and confluent shadows in some areas [45]. Two workers exhibited stage II pneumoconiosis consisting of scattered and confluent mottling in both lungs, and two exhibited stage I pneumoconiosis composed of reticulation and scattered mottling in both lungs.

For seven of the eight workers, blood gas analysis and pulmonary function measurements were reported [45]. The values of vital capacity and maximum breathing capacity, percent arterial blood oxygenation, and arterial partial pressures of oxygen were lower than the predicted values in the workers. The average ventilations/minute/kg e, arterial and alveolar partial pressures of carbon dioxide, and transfer gradient across the lung tissue for oxygen were higher than predicted. This respiratory syndrome indicated that the transfer of CO_2 and the alveolar epithelium was obstructed and that increased ventilation had been established as an adaptive mechanism.

Blood counts were performed on four workers. The results for three were within normal limits, while those for the fourth indicated a slight degree of anemia [45]. Erythrocyte sedimentation rates (ESRs)/hour were between 14 and 38 mm (average 22 mm) for the eight workers with six of the eight values being higher than the normal value of 15 mm/hour. The increase in ESR's is an

WCD 001302

WCD 001303

indication of tissue damage that is not specific for pulmonary lesions. All sputum tests for Mycobacterium tuberculosis were negative.

Alivisatos et al [45] concluded that exposure to talc can result in pneumoconiosis with disturbed lung function, which they considered to be a progressive disease that could lead to pulmonary failure and death. The authors thought that the "tumor-like" appearance on chest X-ray films of the three workers with stage III pneumoconiosis were due to obstruction of the bronchioles by talc that resulted in areas of atelectasis after absorption of the occluded gases into the blood. They also suggested that the unequal distribution of oxygen throughout the lung parenchyma probably caused the higher transfer gradient in workers who had pneumoconiosis. They attributed the rapid development and progression of pneumoconiosis in their patients to the high atmospheric concentrations in the workplace of talc particles with a diameter of 5 µm or less despite the absence of free silica in the talc.

In 1970, El-Shawadi et al [46] reported the incidence of pneumoconiosis among 50 Egyptian workers who milled talc. Chemical analysis of the talc handled in the plant showed 55.8-61% silicate, 28.6-33.13% magnesium oxide, 0.35-5.93% ferric oxide, 1.04-3.05% aluminum oxide, 0.13-1.71% calcium oxide, 0.5-0.32% chromic oxide, and 0.02-0.18% moisture. The talc did not contain free silica. Analysis of air samples collected from the breathing zone of the workers in various work areas revealed mean dust concentrations of 25-111 mppcf and a mean particle size of 45 (um in 95-99% of the samples (the particle size was not reported as length or diameter). Of the 50 men employed at the plant, 6, 18, 17, and 9 were 20-29, 30-39, 40-49, and above 50 years old, respectively, and had varying lengths of exposure to talc.

El-Ghawabi et al [46] found 16 of 50 workers (32%) with pneumoconiosis had been exposed to talc for 15 years or more. Nodular and conglomerate shadows were observed in the chest X-ray films of ten workers (average age 50.4 years) who had been exposed for 17-35 years (average 24.2 years) The remaining 6 (average age 41.8 years) who had been exposed for 4-35 years (average 17.5 years) had linear and reticular opacities. In addition to the 16 workers with pneumoconiosis, 3 others had increased lung markings which the authors suspected to have been indicative of early pneumoconiosis. Two men had shadows in their X-ray films suggestive of tuberculosis, and one of them had extensive pulmonary and pleural fibrosis and slight impairment of lung function. Values of the lung function tests for the rest of the workers were normal. No abnormalities were found in the chest X-ray films of workers <30 years old, which suggested to the researchers that a combination of age and exposure duration influenced the manifestation of the disease.

Sonkowitz [47], in 1970, reported the case of a 31-year-old woman who had worked as a quality control inspector in a plant that manufactured an aerosol talcum product. Part of her job consisted of spraying brief spurts of the contents from the can into the air. She estimated that she sprayed 25-50 cans/hour in this manner without respiratory protection, 1 week out of every 6 for 6 or 7 years. No estimate of her exposure concentration was given.

The woman was examined because of an increasingly severe, persistent and productive cough of approximately 9 months' duration [47]. Her pulmonary vital capacity was approximately 36% of predicted values, and examinations of samples obtained from an open-chest surgery for lung biopsy found lesions including granulomas in a fibrotic stroma. The author reported a successful recovery of the patient over an 18 month period and attributed this to removal

WCD 001304

of the patient from talc exposure and treatment with an antiinflammatory agent (prednisone).

Naa and Gracey [48], in 1972, also reported a case of pulmonary talcosis occurring in a 39-year-old male truck driver who, for 20 years, had dusted himself at least twice daily and for 4 years at least three times a day with a cosmetic talcum powder to relieve recurrent abdominal pain. After he was hospitalized for postprandial vomiting, the man's chest X-ray films revealed a diffuse nodular infiltrate in both lungs. Gross examination of the lungs revealed multiple pale yellow nodules scattered throughout all lobes. In addition, microscopic examination of lung tissue samples revealed diffuse interstitial inflammatory cell accumulation with birefringent needle-like crystals in alveolar spaces and interstitial tissues. The authors concluded that the patient probably had developed pulmonary fibrosis and pneumoconiosis from his extensive use of talcum powder.

(d) Nonrespiratory health effects due to exposure to talc

The formation of granulomas due to talc exposure has been historically of great concern in the medical profession because talc has been widely used as a dusting powder in gloves and rubber articles used in surgical procedures. Talc may contaminate tissues of the body during surgical procedures and may act as a foreign body irritant, resulting in the formation of granulomatous lesions [49,50,51]. The largest part of these occur at the site of direct contact, but within the peritoneal cavity particles may be washed from the site of initial deposition to cause adhesions in distant areas [52]. If such particles should enter the circulatory system, they may cause shock of the nitritoid type and lead to pulmonary and ocular embolism [53,54]. The major

WCD 001305

types of nonrespiratory granulomas that are likely to be of any occupational concern, however, are granulomas of the skin and conjunctivae.

Tye et al [51] reported that a 45-year-old woman developed hundreds of granulomas on the skin after applying talcum powder daily to drained and incised boils on the shoulders, buttocks, and thighs. Transmission electron microscope and X-ray diffraction analysis confirmed the presence of talc within the granulomas. This case demonstrated the possibility of granuloma formation in workers with open skin wounds. Nanda et al [52] found crystals resembling talc in a hemorrhagic lesion in the conjunctivae of a child's left eye. The authors believed that the lesion was caused by airborne particles of baby powder. They succeeded in producing a similar lesion in the conjunctivae of a rabbit with the same baby powder used on the child.

Another potential route for exposure to talc particles is via ingestion in the diet or from respirable and nonrespirable particles trapped in the mucous secretions of the upper respiratory tract, which are eventually swallowed. The effects of talc in the human diet are not known but have recently been the subject of speculation [56,57,58,59].

A 24-nation study of age-adjusted mortality for stomach cancer in 1962-1963 showed that native Japanese men had the highest incidence [56], up to 7 times that of men in the United States [58]. Japanese also consume the largest quantities of talc-coated rice among the 24 nations surveyed. Based on these observations, Merliss [56] theorized that the consumption of rice coated with a talc that contained asbestos was a factor in causing stomach cancer.

Matsuda et al [57] stated that talc was apparently present on the surfaces of unwashed talc-coated rice, on the surfaces of washed and cooked rice, in

WCD 001306

the wash water from the rice, and within the cells of gastric carcinomas from six Japanese patients. The authors studied the morphology of the particles, calculated their magnesium-to-silicon ratios, and noted the similar composition of particles from the rice, the wash water, and tissue samples. They suggested that the talc found in gastric cancer cells from these patients appeared to have been ingested with rice. This finding seems to support the hypothesis of Merliss [561, but has been criticized by Pooley [59] and Stewart [60] on the grounds that the magnesium-to-silicon ratios used by Matsuda et al [57] to identify the talc were not correct, and that the morphologic features of the spherical particles referred to as talc by Matsuda et al were actually characteristic of starch rather than of talc.

A study of 220 stomach cancer patients and 440 hospital controls, all of Japanese descent, in Hawaii by Haenszel et al [61], examined the consumption of specific foods among migrants and their offspring and failed to support the speculation of Merliss [56]. This study not only did not find a dose-response relationship between stomach cancer and rice consumption but found that other dietary factors, such as ingestion of pickled vegetables, had much stronger associations with the incidence of stomach cancer than consumption of rice. The contradictions noted between these studies therefore requires further research concerning the etiology of gastric cancer among the Japanese.

Particles that had properties of surface structure that identified them as either anthophyllite asbestos or talc have been found embedded within human tissues of primary ovarian, endometrical, and cervical carcinomas by Henderson et al [62], using the extraction-replication technique (a method for preparing tissue for electron microscopy). The authors did not comment on how the talc

WCD 001307

may have reached the ovaries and other reproductive tissues. However, they suggested that the impossibility of distinguishing talc from anthophyllite asbestos by this technique rendered impossible the incrimination of talc as the primary cause of the carcinogenic change in any of the tissues.

Epidemiologic Studies

Epidemiologic studies have reported mortality or morbidity in workers exposed to talc both with and without asbestos minerals. The discussion of epidemiologic papers has been organized according to studies of workers exposed to talc without asbestos minerals, and workers exposed to talc with asbestos minerals.

(a) Talc without asbestos minerals

In 1977, Selevan et al [63] reported mortality among 392 workers from several Vermont mines and mills producing talc that did not contain asbestos minerals such as chrysotile and the microscopic fibrous forms of tremolite, anthophyllite, and actinolite. Also, the talc did not contain appreciable quantities of free silica. Other minerals present in these mines included significant quantities of magnesite, chlorite, and dolomite. Historical monitoring data were not adequate to estimate cumulative exposures to talc, but the authors indicated that it had not been uncommon for concentrations of dust to have exceeded 20 mppcf. The available data suggest that prior to 1970, average exposure in mines ranged from 28-122 mppcf, with concentrations as high as 500 mppcf during dry millings. Average concentrations in the mills ranged from 11-131 mppcf, with some measurements in excess of 800 mppcf.

Records of surveys by the Vermont Health Department were used in an

WCD 001308

epidemiologic cohort study [63]. Since 1937, talc workers in Vermont have had chest X-ray films taken annually by the state health department. Workers who had been employed in the Vermont talc industry for at least 1 year between 1940 and 1969 and who had had at least one chest X-ray film taken during the survey were included in the study, and their vital statuses from 1940 to 1975 were ascertained. Mortality was analyzed for the whole study group of 392 workers, and for the 225 employed as millers and the 163 employed as miners for at least 1 year. The groups were not mutually exclusive and 47 workers were included in both categories. Expected mortality from various causes was estimated using age- and time-specific death rates for the white male population of Vermont and of the United States.

At the end of the study, 298 of the 392 talc workers (76%) in the study were alive, 90 (23%) had died, and the vital status of 4 (1%) was unknown [63]. Based on United States death rates, the number of deaths from all causes among Vermont talc workers was elevated (90 observed, 77.32 expected), although not statistically significant.

For the 11 talc workers who died of "other nonmalignant respiratory diseases (ONMRD)", the average duration of talc exposure was 13 years, the average interval between first employment and death was 31 years, and the average age at death was 60.5 years [63]. Eight of the 11 smoked, 1 did not smoke, and information on the smoking habits of the other 2 was unavailable. One of those who died of ONMRD had worked in a talc mine but not in a mill. He had worked in the mine for 16 months, had been exposed to asbestos for 18 months in a previous occupation, was a smoker, and died at the age of 43. A second worker had been exposed to dust in a feldspar quarry, but the other

WCD 001309

nine had not worked previously in a dusty environment, according to health department records.

Based on United States mortality rates, the Standardized Mortality Ratio (SMR) for deaths from ONMRD was 700 in talc millers (7 observed, 0.89 expected, P<0.01), 350 in talc miners (2 observed, 0.56 expected), and 610 in all talc workers (11 observed, 1.79 expected, P<0.01) [63]. Although ONMRD death rates were greater for Vermont men than for men in the entire United States, mortality from ONMRD was still significantly greater for Vermont talc millers than the average mortality among all Vermont men.

Chest X-ray films were available for 8 of the 11 workers who died of ONMRD [63]. Six of the eight X-ray films read following the Union International Centre le Cancer (UICC)/Cincinnati Classification of radiologic appearance of pneumoconiosis) showed small round opacities evenly distributed throughout the lungs. According to the authors, these opacities were consistent with pneumoconiosis. The interpretation and classification of the X-ray films were made without knowledge of the workers' exposure to dust and the readings were consistent with the original interpretation of the X-ray films.

Respiratory cancer was responsible for the deaths of six talc workers: five of these men were miners and the work location of the sixth was undetermined [63]. Two of the men had also been previously employed as millers. Among the 163 men employed as talc miners for at least 1 year, 5 deaths from respiratory cancer were observed, compared with 1.22 expected (P<0.05) on the basis of Vermont mortality rates, and 1.09 expected (P<0.01) on the basis of death rates for the United States. Among the 62 employed as talc miners for 5 or more years, 3 deaths from respiratory cancer were

WCD 001310

observed, compared with 0.81 expected based on the Vermont death rates and
0.71 expected based on the United States death rates. Thus, differences
between numbers of observed and expected deaths from respiratory cancer were
statistically significant for men employed as talc miners for 1 year or more.
The average age at death was 58.2 years, and the average interval between
first employment and death was 27.5 years. The number of years of employment
varied considerably: two men had worked for 2 years, one for 5 years, one for
8.5 years, one for 18.4 years, and one for 40.7 years.

Selevan et al [63] concluded that workers exposed to talc were subject to
an increased risk of death from CNSD, and that most of those who died from
this cause had shown X-ray film evidence of pneumoconiosis while they had been
employed.

Lifetime exposures to respirable airborne talc were probably greater in
the mills than in the mines; however, most of those who died of respiratory
cancer were miners [63]. If the respiratory cancer deaths were associated
with talc exposure, an excess of this cause of death would also have been
expected in the millers. Such an excess did not occur. This suggested that
additional etiological agents, either alone or in combination with talc,
affected the miners. For example, the possible role of exposure to radon-
daughter emissions in the talc mines cannot be eliminated. Historical mean
radon-daughter levels in Vermont talc mines, measured by the Mine Enforcement
and Safety Administration (MESA), ranged from trace quantities to 0.12
working level, with occasional peak readings as high as 1.0 working level.

Recently, Katsnelson and Mokronosova [64] reported a study of an
uncharacterized population of talc workers who worked between 1949 and 1975.

WCD 001311

The talc to which they were exposed was described as containing quartz in concentrations between 0.2% and 1.6%, no tremolite, and nonasbestiform actinolite in only one bedding (of an unknown number), in concentrations <6%. Male workers had relative risks of death due to tumors at all sites, and cancer of the lung and stomach, of 5.1, 4.5, and 3.7, respectively, when compared with risks of death from these same lesions in a control group. The corresponding figures for female workers were 6.4, 0.3, and 5.3. All these relative risks, except that for death due to cancer of the lung in female workers, reportedly were significantly different from 1.0 ($P<0.05$). The investigators concluded that talc dust, even that not containing tremolite or other asbestiform admixtures, is an industrial carcinogen. Because the authors gave no information on the number of male and female workers involved in the study, the concentrations of talc dust to which they were exposed, the durations of exposure, or the date from which the relative risks and their statistical validities were calculated, their conclusion may be questionable.

A study of mortality among miners and millers of talc from the Germanasca and Chisone Valleys in Italy was reported by Rubino et al [34] in 1976. The talc that the workers were exposed to was characterized by the authors as "very pure," with no amphibolic or chrysotilic minerals detected in any talc specimens [34]. Free silica was detected in some, but not all, of the samples from various operations. During the period 1966-1974, free silica in samples of dust from the air within the mines ranged from 12% in areas in which drilling was in progress to 1.5% in areas through which the crude mineral was being transported. In the mills, exposure to free silica in the air was minimal, with recent levels measured at <1% of the total dust. The

WCD 001312

WCD 001313

concentration of total dust in the air was considerably greater in mines before 1960 (16 x the recent concentration) and much greater before 1956 (300 x the recent concentration). Pre-1948 data indicated exposures of up to 798 mppcf in talc mines compared with a maximum of 35 mppcf in talc mills. Dust exposures greatly decreased after 1960 in both mines and mills, and recent counts found 0.8-2.0 mppcf in mines and 2.0-6.0 mppcf in mills. Using company and town records, the investigators individually matched 1,346 miners (89%) and 438 millers (92%) whose vital status in 1940 to mid-1974 was known with controls of the same age from a nearby agricultural town. Using proportional mortality comparisons, Rubino et al concluded that exposure to silica in talc mines increased the risk of death from respiratory disease, that talc mining entailed no increase in the risk of death from any other cause, and that pure talc was not carcinogenic.

Rubino and a somewhat different group of coworkers [65], also reanalyzed the data in the study above [34] in a subsequent publication using Italian national statistics for comparison. The comparisons did not show any statistically significant increase in the incidence of cancer at any site. However, the SMR for deaths in miners from nonmalignant respiratory diseases increased as cumulative exposures to respirable talc increased. The exposure of workers to talc dust was measured at different times. Since some workers were exposed to different dust concentrations during variable periods of time, the authors calculated the cumulative exposure in the following manner: the concentration of dust was multiplied by the number of years of exposure at that concentration and was then added to other periods of exposure calculated in the same way, the result was expressed as the cumulative exposure. The

group of miners exposed for a total accumulated dose of <1700 mppcf-years had an SMR of 191 (15 cases observed, 6.3 expected), the group exposed for 1700-5665 mppcf-years had an SMR of 316 (30 cases observed, 9.5 expected) and the group exposed for >5665 mppcf-years had an SMR of 418 (64 observed, 15.3 expected). The SMR also increased as the latent periods between first exposure and death increased. In millers, however, the distribution of deaths from nonmalignant respiratory disease could not be shown to be related either to cumulative exposures to talc alone ranging from <142 to >424 mppcf-years or to the latent period.

Rubino et al [85] also reported the incidence of X-ray film changes in a group of 43 millers exposed to talc dust not containing asbestos and that contained approximately 1% or less free silica. The X-ray films were evaluated in accordance with the International Classification of Radiographs of Pneumoconiosis (revised 1958), and the cumulative dust exposure was calculated and reported as mppcf-years. X-ray film abnormalities were not observed for any of the workers exposed for <20 mppcf-years; however, 3 of 11 workers (27%) exposed in the range of 101-320 mppcf-years had initial or more advanced X-ray film changes (0/1 or greater), that showed "suspect pneumoconiosis" according to the classification system [66]. Eighty-two percent of workers with exposure levels >320 mppcf-years had at least initial X-ray film signs of pneumoconiosis with 4 workers (36%) classified as 0/1 and 3 workers (27%) classified as 1/0. X-ray films definitely consistent with pneumoconiosis (1/1 or greater) were observed only in the group with exposure levels >320 mppcf-years, with 2 of 11 workers (18%) being so classified. Rubino et al stated that X-ray film opacities consistent with pneumoconiosis

WCD 001314

exposure to asbestos and a severe risk of developing mesothelioma and other cancers. The latency period between exposure and the onset of symptoms is usually 20 to 50 years. Mesothelioma is a rare cancer of the thin membrane lining the chest cavity (pleura) and abdomen (peritoneum). Symptoms usually do not appear until 30 to 40 years after exposure to asbestos. Mesothelioma is a highly fatal disease with a median survival time of only 12 to 21 months after diagnosis. Because the latency period for mesothelioma is typically 30 to 40 years, plaintiff could not have been diagnosed with mesothelioma until 2007 at the earliest.

Because plaintiff was not diagnosed with mesothelioma until 2007, plaintiff's claims are timely under the discovery rule, which tolls the statute of limitations until a reasonably diligent person knew or should have known of the facts giving rise to a cause of action. Plaintiff could not have known of the facts giving rise to a cause of action for mesothelioma before 2007 because plaintiff was not diagnosed with mesothelioma before 2007, and because plaintiff had no knowledge before 2007 that exposure to asbestos could cause mesothelioma.

Defendants knew or should have known that exposure to asbestos could cause mesothelioma and other serious illnesses, and that members of the general public who were exposed to asbestos would suffer injuries as a result of their exposure. Defendants knew or should have known that exposure to asbestos was especially dangerous and likely to cause disease and death in persons exposed to asbestos for prolonged periods of time, or in persons exposed to asbestos on a regular basis over some period of time. Defendants knew or should have known that exposure to asbestos was especially dangerous and likely to cause disease and death in persons exposed to asbestos in combination with other substances, such as cigarette smoke.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products. Defendants knew or should have known that asbestos was a hazardous substance and that exposure to asbestos materials would result in harm to users of asbestos products and persons working in the vicinity of asbestos products.

WCD 001315

(range, 0.47-3.85 mg/cu m). The authors stated that exposures over the past twenty years probably had not changed much, although they presented no evidence for this observation.

The 80 workers exposed to respirable talc were matched for control purposes by age and length of employment with 180 men from other areas of the plants who had not been exposed to talc, curing fumes, or carbon black [17]. Twenty-five of the 80 workers worked in a plant in which they were not exposed to other known respiratory hazards and 55 worked in another plant where they were also exposed to rubber curing fumes. Information on previous occupations, medical histories, smoking habits, and respiratory symptoms was obtained during workshifts by trained interviewers using a modified version of a questionnaire developed by the British Medical Research Council (MRC). Indices of pulmonary function, including FEV 1 and flowrates at 12.5%, 25%, and 50% of FVC, were measured with a spirometer during workshifts. FEV 1 and FVC were also measured for 28 workers exposed to talc before and after the first workshift following a 2-day weekend. Posteroanterior and lateral chest X-ray films were made of all but four workers.

Factors that could have influenced respiratory symptoms, such as age, height, length of employment, and smoking habits, were similar for both the talc-exposed and the control-group workers [17]. The percentage of workers who were former or current cigarette or cigar smokers was similar in the two groups. Those in the talc-exposed group had smoked for an average of 12.8 years and those in the control group for an average of 12.7 years. Percentages of respiratory symptoms in smokers and nonsmokers in the group exposed to talc and in the control group are summarized in Table III-6 [17].

WCD 001316

TABLE III-6

PERCENTAGES OF TALC-EXPOSED WORKERS AND CONTROLS WITH RESPIRATORY SYMPTOMS*

Symptoms	Nonsmokers			Former and Current Smokers***		
	Talc	Control	P**	Talc	Control	P**
No. of Workers	(22)	(51)		(58)	(38)	
Chronic bronchitis symptoms (mucous hypersecretion)						
Cough for 3 mo	4.5	-	NS	25.9	10.1	.006
Phlegm for >3 mo	18.2	5.9	NS	36.2	15.2	.002
Obstructive respiratory disease symptoms, wheezing most days and nights	-	2.0	NS	22.4	**6.5**	.03
COLD****	-	5.9	NS	24.1	**11.6**	.003

*Talc-exposed workers and controls employed in rubber plant. Workers exposed to industrial grade talc containing <1% free silica for av 8.9 yr. Most workers exposed to respirable talc at about 1 mg/cu m at end of study.

**Based on Fisher's exact test.

***Former or current smokers of cigarettes, cigars, or pipes

****Chronic obstructive lung disease (COLD), wheezing most days and nights, grade 3 labored breathing, or FEV 1/FVC x 100 less than 60%.

Adapted from Fine et al [17]

Among both smokers and nonsmokers, more workers exposed to talc had symptoms of chronic bronchitis indicative of mucus hypersecretion than did the controls, although the increase was statistically significant ($P<0.004$) only for smokers [17]. The percentage of workers who experienced wheezing during most days and nights was significantly increased ($P<0.008$) among those exposed to talc who also smoked, but not in those who had never smoked. The percentage of men with one or more positive indicators of chronic obstructive

WCD 001317

lung disease (COLD) was greater in talc workers who smoked than in the corresponding controls, largely because a greater percentage of the smokers were subject to wheezing. The percentage of workers with colds during winter was slightly greater in exposed workers than in controls, although percentages of workers with past medical histories of bronchitis, pneumonia, or asthma were similar in both groups. Because the incidence of respiratory symptoms was greater for workers exposed both to talc and to fumes from curing rubber and for those exposed to talc alone than for corresponding control workers, Fine et al concluded that workplace exposure to talc was associated with increases in these symptoms. The magnitude of these increases may have been affected by exposure to the curing fumes, however, since Fine and Peters [67] had shown in a previous study that exposure to such fumes was also associated with an increase in symptoms of chronic bronchitis.

Comparisons of pulmonary function in talc workers and controls were limited to white men more than 24 years old [17]. Of all pulmonary function measurements, only adjusted FEV 1 was significantly different between the exposed and control groups, and then only for those exposed more than 10 years. For the 27 workers exposed for 10 or more years to talc and, in some instances, to curing fumes as well, measurements of FEV 1 were an average of 211 cc lower than predicted values derived from the control group after adjustment for differences in age, height, and smoking habits. Values of FEV 1 for workers exposed to talc <10 years were an average of 72 cc higher than predicted values. Coefficients for age, height, and years of cigarette smoking were statistically significant predictors in the regression equation for FEV 1 ($P<0.004$, $P<0.006$ and $P<0.005$, respectively) for both talc workers and

WCD 001318

controls, indicating that these factors are important determinants of pulmonary function in these populations. The regression coefficient for years of exposure to talc was a statistically significant predictor (P<0.05) in the FEV 1 regression equation for workers exposed to talc, but the regression coefficient for duration of employment of controls was not a significant predictor of FEV 1. The regression analysis for the 58 men exposed to talc indicated that, for each year of exposure to respirable talc dust, the workers' FEV 1 decreased an average of 38 cc more than would have been expected on the basis of age and smoking habits.

These findings indicated that FEV 1 decreased progressively as years of workplace exposure to talc increased [17]. Since measurements of FVC were not affected by exposure duration, the principal effect of exposure to talc on the lungs appeared to be obstructive. None of the workers exposed to talc had chest X-ray film findings definitely consistent with pneumoconiosis, but workers in this study were probably exposed to lower concentrations of talc than were workers in other studies that reported X-ray film findings definitely consistent with pneumoconiosis [63,65].

Since workplace exposure to respirable talc dust at these concentrations apparently led to progressive deterioration of lung function, Fine et al [17] suggested that cumulative exposure to a respirable talc dust should be restricted to 10-20 mg years during a working lifetime of 40 years. They suggested that a TLV of 0.25 mg/cu m should limit impairment of lung function and decrease the excessive incidence of respiratory symptoms in workers exposed to talc. The small number of workers involved in this study and the uncertainty of cumulative exposure levels for individual workers casts some

WCD 001319

doubt on the accuracy of this estimate of a safe exposure level. This study does suggest an increased risk of respiratory disease among talc workers who smoke and a possible effect on FEV 1 in workers exposed in a range of 0.47-3.38 mg/cu m for more than 10 years.

In 1975 and 1976, Wagman et al [68] investigated the signs and symptoms of respiratory disease in workers employed at three major Vermont talc companies that processed talc. The free silica content of talc dust at Vermont operations was estimated to be <50 (ubq/cu m [20]. A modified British Medical Research Council questionnaire was used to obtain information from each worker on past medical history, lifetime smoking history, and the severity of symptoms indicative of chronic bronchitis. Chest X-ray films were evaluated by at least two readers using the International Labor Organization (ILO)/UICC classification system. Any discrepancies between the first two readings were resolved by a third reader. Pulmonary function measurements (FEV 1, FVC, MMEF, TLC) were also made.

Of the 174 employed at the 3 Vermont talc plants in 1975, 142 (82%) were included in the 1975 survey; the other 32 were either not available or refused to participate [68]. The 1976 survey included 127 (89%) of the 142 examined in the first survey. Findings from 117 workers in the 1975 survey were studied in a cross-sectional analysis, and findings from 103 workers in both surveys were compared in a longitudinal analysis designed to assess whether there had been a change in the signs or symptoms of chronic respiratory impairment within 1 year. Of the 117 in the 1975 study, the average age was 40.6 years; they had smoked an average of 21.9 years and had been employed in talc operations for an average of 8.5 years.

WCD 001320

Although they did not discuss the point in detail, the authors [68] indicated that workers in the 1975 study who had been exposed to talc and who had symptoms of respiratory impairment also appeared to have had more impairment of lung function than did those exposed to talc who had no symptoms. Abnormal lung sounds were heard in 12 of the 117 workers (10%) in the 1935 study. Five had rales, one a pleural rub, two had coarse rhonchi suggestive of colds, and four had minimal changes that were considered transitory. For the whole 1975 group (142), the average FEV 1 was slightly less, and the average FVC was slightly greater than expected: FEV 1 was 96.6% of the expected value and FVC was 103.6% of the expected value. The ratio of percent observed FEV 1 to percent observed FVC was 0.93%. These findings suggested to Wagman et al [68] that some factor was affecting FEV 1 selectively in the study population.

Wagman et al [68] found that FEV 1 decreased from 101.4% of the predicted value in men exposed to talc for <5 years, to 87.9% in men exposed for 20 or more years. Using the mean FEV 1 of 3.61 liters for the study population, the difference between 101.4% and 87.9% of FEV 1 was 490 ml. According to studies [69,70] cited by Wagman et al, FEV 1 values generally decrease by about 10-17 ml for each year of cigarette smoking. Differences in cigarette smoking would account for only 180-306 of the 490-ml difference in FEV 1 between the talc workers employed for <5 and for >20 years (37-62%). Since FEV 1 was 104.5% of the predicted value in the 36 talc workers who had never smoked and 97.3% in former smokers, the authors suggested that inhaled talc and cigarette smoke may interact physiologically, causing FEV 1 to decrease more than would be expected from cigarette smoking alone.

WCD 001321

Between 1975 and 1976, FEV 1 values decreased by an average of 15 ml/year in workers exposed to talc who had never smoked, by 48 ml/year in former smokers, and by 60 ml/year in current smokers [65]. When smoking histories of workers exposed to talc were compared with their current geometric mean dust exposures, the differences in exposures were small (nonsmokers were exposed at an average of 1.57 mg/cu m of respirable talc dust, former smokers at 1.75 mg/cu m, and current smokers at 1.91 mg/cu m). However, variations between current exposure levels, smoking histories, and changes in FEV 1 were apparently quite substantial, so that decreases in FEV 1 could not be related to current exposure levels. The authors stated that the current exposure estimates were not reliable and could be considered misleading due to the wide range of exposure levels for different jobs and the frequent change of individual workers between jobs. The authors also pointed out that current exposure estimates could not be used to accurately determine previous or cumulative exposures since major changes in engineering control techniques had been instituted before the study began. Using stepwise multiple regression analysis, it was found that neither smoking histories nor current exposures were significant predictors of changes in FEV 1. The authors suggested that this population be followed for a longer time, perhaps 3 years, to determine more reliably the effect of exposure to talc on lung function.

Of the 78 workers in the 1975 study with chest X-ray films, 36 (46%) had positive findings indicative of pneumoconiosis and 14 (18%) had findings definitely consistent with pneumoconiosis [65]. Those showing small round or irregular opacities indicative of pneumoconiosis generally had lower lung function values than those with normal X-ray films, but the authors indicated

WCD 001322

that the differences were not statistically significant.

Hagan et al [68] concluded that there appeared to be an impact on this population's lung function most likely as a result of 1 year's workplace exposure to talc. Although a safe level of exposure could not be reliably determined, the authors concluded that a safe level appeared to be near the range of 1-2 mg/cu m. They suggested that history of exposure to talc, as indicated by number of years employed, and smoking history, as indicated by number of years smoking had occurred, seemed to be of equal importance in predicting FEV 1 in workers exposed to talc after correction for age and height. Hagan et al also concluded that talc did not appear to affect lung function in workers who had never smoked.

(b) Talc with asbestos minerals

Dement et al [18] reported morbidity and mortality studies of workers who mined or milled talc containing microscopic fibrous forms of tremolite and anthophyllite. Analysis of talc products in this study found 37-50% tremolite, 4.5-13% anthophyllite and 0.35-2.6% free silica. Identification of airborne fibers longer than 5 μm in length, determined by electron microscopy in mines and mills, showed 93% were anthophyllite fibers and only 7% were tremolite fibers. Respirable dust exposures ranged from 0.25-2.06 mg/cu m.

In the morbidity study, Dement et al [18] analyzed the signs and symptoms of chronic respiratory impairment in miners and millers exposed to talc containing asbestos minerals. Of the 156 men employed at the one plant studied, 121 (78%) with an average duration of employment of 10.2 years participated in the study.

Measurements of lung function, symptoms of respiratory disease, and X-ray

WCD 001323

findings indicative of pneumoconiosis in talc workers were compared with findings from similar NIOSH studies of chronic respiratory impairment in 9,347 coal miners and 1,095 potash miners [16]. Also, the extent of respiratory disease in workers exposed to talc could be assessed relative to the extent of disease in the two other groups of workers. For purposes of comparison, findings for coal and potash workers were adjusted by age (10-year intervals), by height (10-cm intervals), by smoking history (current, former, or never), and by years of employment (<15 years and equal to or more than 15 years) to the distribution of these variables for the group of 121 talc workers.

In general, the prevalences of cough and phlegm were greater in talc workers than in coal or potash workers [16]. For the 82 talc workers employed for <15 years, the incidences of cough and phlegm were significantly greater than in coal or potash workers employed for <15 years. For the 39 employed in talc operations for 15 or more years, the prevalence of cough was also significantly greater than for potash miners employed for >15 years, but about the same as for coal miners employed >15 years. The incidence of phlegm was about the same for potash and talc miners employed for 15 or more years, but was significantly greater ($P<0.05$) in coal miners than in talc workers. Differences in the prevalence of X-ray film abnormalities among the three groups and with length of employment in talc operations were more substantial than were differences in respiratory symptoms. In workers employed for <15 years, the prevalence of X-ray film abnormalities was <2% for all three groups of workers combined.

Pleural thickening (grade 1 or 2) was found in 1.2% (1 or 2) of the group of talc workers, but in only 0.3% of the coal miners employed for <15 years.

WCD 001324

In contrast, evidence of pleural thickening was significantly more prevalent (P<0.05) in 33% (13 of 39) of the talc workers employed for 15 or more years compared with 1.5% of the coal miners and 3.7% of the potash miners. Pleural thickening seemed not to be associated with cigarette smoking and was not found in workers younger than 40 years. None of the talc, coal, and potash workers employed for <15 years had X-ray film evidence of pleural calcification. Four of the talc workers (10.3%) employed for 15 or more years showed evidence of irregular opacities in their chest X-ray films, compared with 3.6% of the coal miners and 0.4% of the potash miners (P<0.005). One talc worker employed for 15 or more years had a rounded opacity (2.6%), compared with 14.5% of the coal miners and 1.6% of the potash miners. For the 93 talc workers with no previous workplace exposure to talc in other mines and mills, the findings were usually similar to those for the total workforce of 121 talc workers. The one finding that was statistically significant was evidence of pleural thickening found in 31% of the talc workers employed at the plant under study but in only 1.5% of the coal miners (P<0.05) and 4.4% of the potash miners (P<0.05) employed for 15 or more years.

Most measurements of pulmonary function, including FEV 1 and FVC, yielded lower values for talc workers than for coal or potash workers (16). For the 121 talc workers, the observed mean FEV 1 was 6% less than the mean FEV 1 predicted values based on measurements in both coal and potash miners. Mean FVC measurements for the 121 talc workers were 6% and 8% less than predicted, based on values for potash and coal miners, respectively. For each 10 mg of total cumulative exposure, the mean percent of predicted FEV 1 in the 121 talc workers decreased by 3.8% compared with that of coal miners (P<0.05) and by

WCD 001325

6.2% compared with potash miners (P<0.005). This finding, combined with the increased incidence of X-ray file markings and increased incidence of respiratory symptoms, indicated a more severe effect in workers exposed to talc with asbestos compared to workers exposed at similar concentrations of potash or coal dust.

Since evidence of pleural thickening was the major X-ray file finding of the study, Dement et al [18] compared information on symptoms, pulmonary function, and exposure in talc workers with grade 1 or 2 pleural thickening with information for talc workers without pleural thickening. For talc workers 50-59 years old who had been employed for 15 or more years, the prevalence of cough and phlegm was significantly greater in those with grade 2 pleural thickening than in unaffected workers. However, the prevalence of these symptoms was significantly lower in those with grade 1 pleural thickening than in unaffected workers. Cumulative exposure to fibers was somewhat greater in talc workers with pleural thickening than in unaffected workers, although average yearly exposures were similar for the two groups. Cumulative exposures to particulates were actually slightly lower for affected than for unaffected workers, and there were no differences in cigarette smoking habits between these two groups of talc workers. In talc workers 50-59 years old, those with pleural thickening had begun to work at an earlier age and had a lower percent of predicted FEV 1 and FVC values than workers not showing pleural thickening.

In conclusion, this morbidity study [18] showed that actively employed workers exposed to talc containing microscopic fibrous forms of anthophyllite and tremolite had an increased prevalence of cough and phlegm, and signs of

WCD 001326

respiratory impairment, including reduced FEV 1 and FVC. Also, after 15 years of employment, nearly one-third of the workers showed X-ray film evidence of lung opacities and pleural thickening.

Morbidity studies of workers in upstate New York exposed to talc with asbestos were also reported by Nenzite et al (71) and Kleinfeld et al (72). Both groups also reported X-ray film evidence of fibrosis, decreased lung function measurements and increased incidence of signs and symptoms of respiratory disease among these workers.

Dement et al (10) also studied the mortality of workers employed at the mine and mill in New York State where they had conducted the morbidity study discussed above. All men first employed at either the mine or the mill between 1941 and the end of 1959 were included in the study, and their vital status was determined as of June 30, 1975. Of the 398 workers studied, 202 (nearly 51%) had worked at the mine or mill for <1 year, 90 (nearly 23%) for 1-10 years, and 106 (nearly 27%) for >10 years. By the end of the study, 74 (19%) of the workers had died, 308 (77%) were known to be alive, and the status of 16 (4%) was unknown. The 398 workers had accumulated a total of 8,782 person-years at risk until the end of the study on August 30, 1975, or the date of death, whichever came first. Table III-7 summarizes the deaths observed from the study cohort and those expected on the basis of death rates for the white male population of United States.

WCD 001327

TABLE III-7

DEATHS IN MINERS AND MILLERS OF TALC FROM ST. LAWRENCE COUNTY, NEW YORK*

Cause of Death	Observed	Expected	O/E
Cancer	19*	10.5	1.8**
Respiratory	10	3.2	3.1**
Digestive	3	2.9	1.0
Lymphatic and hematopoietic	4	1.3	3.1
Other	2	3.1	0.6
Nonmalignant respiratory disease	2	2.8	2.9**
ONMRD***	5	1.4	3.6**
Influenza and pneumonia	3	1.4	2.1
Tuberculosis	1	0.57	5.3**
Heart disease	26	25.4	1.0
Accidents	10	6.7	1.5
Other causes	8	16.4	0.49**
All causes	74	62.4	1.2

*Three additional workers in the study died of lung cancer, but these death were not included in the tabulations since they occurred after June 30, 1968, the end of the follow-up period.

**P<0.05

***Other nonmalignant respiratory diseases

Adapted from Dement et al [18]

The O/E ratios of death were elevated for influenza and pneumonia, respiratory tuberculosis, ONMRD, and cancers of the respiratory system; all but the first being significantly elevated (P<0.05) [18]. The observed number of deaths from heart disease and from cancer of the digestive system were nearly identical to the expected values. The O/E ratios for cancer of the

WCD 001328

lymphatic and hematopoietic tissues and for accidents were elevated, although
not significantly.

Dement et al [18] concluded that workers employed at this talc mine and mill were subject to excessive risk of mortality from lung cancer and from nonmalignant respiratory disease. Workers at this mine and mill were exposed to talc containing microscopic fibrous forms of tremolite and anthophyllite, but little free silica. The authors suspected that the microscopic fibrous forms of tremolite and anthophyllite were the prime etiologic agents associated with the increase in respiratory cancer and nonmalignant respiratory disease among these talc workers. Since the one worker in this study [18] who developed mesothelioma had also worked in the construction industry where he could have been exposed to other types of asbestos minerals, Dement et al did not attribute this case to exposure to microscopic fibrous forms of tremolite or anthophyllite. They suggested, however, that the possibility that the relationship between exposure to microscopic fibrous forms of tremolite or anthophyllite and mesothelioma should be studied further. The authors noted that four of nine workers who died of lung cancer had worked at the plant studied for <1 year. Only one of them had worked previously at another talc plant, for only 5 months. The authors thought that it was possible that brief exposures at elevated concentrations of asbestos minerals increase the risk of death from lung cancer and noted that one such observation had been previously reported [15].

A proportionate mortality study of workers exposed to talc that contained asbestos minerals was first reported in 1967 [73] and was updated by Kleinfeld et al in 1974 [74]. The workers employed in mines and mills were exposed to

WCD 001329

talc that contained serpentine (not characterized) and microscopic fibrous forms of tremolite and anthophyllite.

Included in the study were 260 workers who either had been exposed for at least 15 years between 1960 and 1969 or who had been employed in 1940 after previously having been exposed to talc dust for at least 15 years [74]. The authors reviewed many sources of information, including death certificates and records of the companies, of appropriate hospitals, of private physicians, and of the New York State Industrial Hygiene department. They found that 106 of the 260 talc workers (41%) had died between 1940 and 1969. The average age at death was 60.3 years (range 33-84 years), and the average duration of exposure to talc dust was 24.1 years (range 15-47 years). The percentage of deaths from cardiac disease and from cancer of the respiratory and digestive tracts in these workers was compared with the percentages of deaths from these causes among white males in the United States in 1955, the median year for the 100 deaths.

Thirteen workers exposed to talc died of malignancies of the respiratory system, 12 from carcinoma of the lungs and 1 from fibrosarcoma of the pleura [74]. Thus, 12% of the talc workers died of respiratory malignancies, compared with 3.7% of white males in the United States who died in 1955; the more-than-threefold difference between the percentages is statistically significant (P<0.05). Eight of these 106 talc workers (7.4%) died of cancer of the gastrointestinal tract compared with 6.5% of the general male population (P>0.05). Conversely, only 27.8% of the talc workers died of cardiac disease compared with 45.8% of the controls (P<0.05). Twenty-nine talc workers died of pneumoconiosis or its complications, 20 from cor

WCD 001330

pulmonale, 5 from advanced tuberculosis, and 4 from bronchopneumonia. The
2769 percentage of men in the general population who died of nonmalignant
2770 respiratory disease was not reported, but the study suggested that workers
2771 exposed to talc that contained tremolite were more likely to die of diseases
2773 of the respiratory system than was the general population.

2776 Estimates of the risk of developing malignant or nonmalignant respiratory
2777 disease in workers exposed to talc that contained microscopic fibrous forms of
2778 tremolite and anthophyllite were not provided by this study [74]. The
2780 procedures used to identify deaths of talc workers were not discussed in
2781 detail, and the smoking history of the population was not investigated.
2782 Information on causes of death in the general population was taken from death
2784 certificates. If the information on the mortality of workers exposed to talc
2785 had been obtained from sources other than death certificates, the comparison
2786 of the mortality experiences of these two groups would not be valid.

2789 In addition, the distribution of deaths in the general population in 1955
2790 may not have reflected the distribution of deaths between 1940 and 1960 [74].
2791 The lower percentage of deaths due to heart disease of workers exposed to talc
2793 might have been related to increases in the percentages of deaths from other
2794 causes, such as malignant and nonmalignant respiratory disease, rather than to
2795 an actual decrease in the risk of death from heart disease. The authors
2797 believed that deaths from lung cancer would have occurred less frequently in
2798 workers employed after 1945, when concentrations of talc were reduced in both
2800 the mines and the mills. Although this may be a reasonable assumption, the
2801 data presented by these investigators are not sufficient to support this
2802 conclusion. Since the average latent period between first exposure and death

WCD 001331

WCD 001332

from respiratory cancer was 24 years, for workers first employed after 1945 could have died of respiratory cancer before the end of the study period in 1969. Although the estimate is imprecise, the greater-than-threefold increase in deaths from respiratory cancer is of sufficient magnitude to suggest that this finding is not an artifact. It appears from this study, therefore, that workplace exposure to talc that contained the microscopic fibrous forms of tremolite and anthophyllite increased the risk of developing cancer of the respiratory system in the population studied.

Animal Toxicity

Experiments with animals have demonstrated that exposure to talc can induce biologic effects in animals similar to those found in humans exposed to talc. For purposes of comparison, studies in this section will be presented in the following order: inhalation, intratracheal, intraperitoneal and dermal studies, distribution and elimination studies, carcinogenicity, mutagenicity, teratogenicity and effects on reproduction.

(a) Inhalation studies

In 1977, Wehner et al [75] reported a study in which hamsters were exposed to an aerosol of cosmetic talc characterized as 95% pure talc with trace quantities of carbonates and chlorite. Groups of 6-week-old male and female hamsters were exposed for 3, 30, and 150 minutes/day for 30 days and 7-week-old male and female hamsters were exposed for 30 or 150 minutes/day for 300 days (or until death). The mean total aerosol concentration was 37.1 mg/cu m ±7.4 (SD) for the 6-week-old hamsters and 27.8 mg/cu m ±3.4 (SD) for the seven-week-old ones and the mean mass aerodynamic diameter of the respirable

fraction was 3-6 (u)m.

Control animals were exposed only to filtered room air but were kept in identical rooms with identical food, temperature, and humidity and were transferred daily to a similar exposure chamber for the specified period of time to control for the stress of handling. Animals were kept under observation until 90% of the group had died naturally, at which time the survivors of the group were killed.

In regard to body weight, lifespan, and the type, incidence, and severity of lesions observed at necropsy, the authors [75] reported no statistically significant effects from these exposure concentrations or durations. However, talc particles were found in the lung parenchyma 3.5 months after the last exposure and females exposed at the highest concentration of talc experienced increases in the incidence of focal alveolar hyperplasia, histocytosis, and interstitial pneumonia. The widespread occurrence of interstitial pneumonia in both the exposed and control hamsters (46% in the control group, 50% in the exposed group) complicates interpretation of this study but the highest exposure concentrations in this experiment was probably near that required to produce an observable effect in this species. The higher incidence of pulmonary lesions in exposed females compared with that in the males suggests that further study is necessary to investigate whether a potential sex difference in risk exists.

Wagner et al [76] reported the results of an experiment in which rats were exposed to talc by inhalation. The talc used was of Italian origin with no asbestos fibers and <1% free silica. The talc consisted of about 92% pure talc with traces of chlorite (3%) and carbonate minerals (1%) and had a mean

WCD 001333

particle size of 25 (u). Ninety-six rats (48 males and 48 females) were
2879 exposed at a mean respirable concentration of 10.8 mg/cu m for 7.5 hours a
2880 day, 5 days a week, for either 3 months, 6 months, or 12 months. Ninety-six
2881 control animals (also 48 of each sex) not exposed to talc were necropsied
2882 along with the exposed groups. The rats were killed either 10 days or 1 year
2883 after exposure or when they appeared to be distressed.

2885 The author (76) examined sections of both lungs of each rat without
2886 knowledge of extent of exposure. The tissues were graded according to a
2887 seven-point scale, with 1 corresponding to no fibrosis; 2, minimal; 4, slight;
2888 6, moderate; and 8, severe. The mean fibrosis scores for rats sacrificed 10
2889 days after final exposure were 2.2 for rats exposed 3 months, 2.7 for rats
2890 exposed 6 months, and 3.4 for those exposed 12 months. Rats examined 1 year
2891 after final exposure had mean scores of 2.4, 3.4, and 4.6 for 3, 6, and 12
2892 months groups, respectively. The mean fibrosis scores for the control animals
2893 ranged from 1.3 to 1.9. Although the authors indicated that this was a
2894 preliminary study, it indicates a progression of fibrosis with increasing
2895 duration of exposure that is not reversed by cessation of exposure.

2898 In 1977, Bettge-Weenke (77) published a study on the effects of exposure
2898 to talc on 3-month-old male rats. The author described the two talc
2899 substances used in the experiments as "technical" grade and "pharmaceutical"
2901 grade talcs but did not report precise mineral compositions. The particles of
2902 about 60% of the technical grade talc and of 87% of the pharmaceutical grade
2903 talc were <5 (u)m in size, with 30% and 31% being <1 (u)m in diameter,
2904 respectively. The experiment involved 85 rats (individual weights ranging from
2906 130 to 170 g); 15 control animals were kept in separate talc-free chambers

WCD 001334

while 35 rats were exposed to technical and 35 to pharmaceutical talc 6 days/week for 9 months. The author determined concentrations of talc dust in the chambers by a gravimetric method. The chambers were run on a schedule which could be characterized as intermittently static. The average dust concentration in the chambers at the time talc was introduced was 346 mg/cu m for technical grade talc and 383 mg/cu m for pharmaceutical grade talc, and after 1 hour the concentrations decreased to 30 mg/cu m and 23 mg/cu m for the two talcs, respectively. Talc was reintroduced into the chambers at the end of each hour.

Seven rats from each of the exposed groups and three rats from the control group were killed after 7 days, 14 days, 3 months, 6 months, and 9 months, and the pulmonary organs were examined at necropsy (771). The author reported no changes in the group exposed for 7 days, but gross examinations of the other groups showed pronounced changes in the respiratory tract. After 14 days of exposure, microscopic examinations showed that both groups of animals had developed nonspecific inflammation in the respiratory tract. After 6-9 months, the inflammation in the larynx, trachea, and bronchi was considered chronic and atrophic. In the lungs of both groups of animals, talc dust caused a fibrocellular reaction that produced a focal fibrosis and emphysema. Selikoff-Iwanski also noted a granulomatous cellular reaction in the lymph nodes. After 3-6 months of exposure, the animals had phagocytes in the alveolar lumina. These phagocytes later formed cellular nodules that developed into fibrocellular nodules by the end of 9 months. In addition, the investigator observed that as the pulmonary arterial walls thickened, the lumina narrowed. These changes were present in both groups of exposed animals but not in the

WCD 001335

control group.

The author [77] concluded that both technical and pharmaceutical grade talc dusts produced pronounced changes throughout the respiratory system at the concentrations at which these animals were exposed and that both grades of talc induced similar respiratory changes, which increased in severity as the exposure duration increased.

(b) Intratracheal studies

Schepers and Durken [78] also conducted a series of experiments using various combinations of quartz, serpentine (not characterized), microscopic fibrous forms of tremolite, anthophyllite, and Georgia talc. The talc and tremolite both consisted of particles or fibers <3 (um in length. In one experiment, the researchers injected intratracheally a total dose of 150 mg of talc dust into 13 adult guinea pigs. After 1 month of exposure necropsies was performed on several animals and microscopic examination of sections of their lungs revealed irregularly distributed confluent pneumonic patches, which contained macrophages that had engulfed particles of talc. After 1-2 years, the surviving animals had bronchiolectasis, bronchitis, perivascular and peribronchial cellular proliferation and fibrosis, and fibrocellular pleural sclerosis.

When 75 mg of a mixture of 50% talc, 30% tremolite (with fibers <3 (um in length), and 20% anthophyllite (with fibers of 20-50 (um in length), was injected intratracheally into six guinea pigs, subpleural, peribronchicler, and perivascular macrophages and fibrocytic proliferation were seen within a year [78]. A dust mixture containing 43% talc, 20% tremolite (with fibers <3 (um in length), 17% anthophyllite (with fibers of 20-50 (um in length), and

WCD 001336

WCD 001337

14% quartz induced massive exuberant macrophage and fibrocytic cellular
2981 proliferation, bronchiectasis, and bronchitis with minimum fibrosis in six
2982 guinea pigs within 1 year of exposure.

2985 Among the other mineral dusts tested seperately by the authors [78],
2986 exposure to serpentine caused chronic bronchitis and bronchiolectasis. The
2988 authors concluded that talc containing anthophyllite with fibers 20-50 (u)m in
2989 length exhibited maximum fibrogenic effect. This study demonstrated that talc
2991 with or without free silica or asbestos induced a macrophagic response and
2993 fibrosis. The authors concluded that the presence of asbestos minerals with
2995 long fibers resulted in more rapidly developing lesions of greater severity
2996 than that of talc alone.

2998 Gross et al [79] investigated pulmonary responses of rats exposed to two
2999 different talc dusts which contained tremolite. One talc dust had a high
3001 content of nickel and contained fibers with an average diameter of 0.2 (u)m.
3002 Another dust had a low content of nickel and a mean fiber diameter of 0.1
3004 (u)m. Twenty-five rats were each given a single dose of .25 mg of the talc
3005 with a high nickel content by intratracheal injection and 25 other rats
3007 received the same dose of the talc with low nickel content. Four rats from
3009 each group were killed and examined 4 days after injection; the rest were
3010 examined after they had died naturally.

3012 The lungs of all rats examined 4 days after injection had polypoid
3013 proliferative acute inflammation involving small bronchi and bronchioles [79].
3014 Within a few months, the initially argyrophillic stroma were converted into
3015 dense collagenous scars that often deformed the bronchi and bronchioles. The
3017 investigators found that similar proliferative, nonreversible lesions were

produced by both talc dusts.

(c) Intraperitoneal and dermal studies

Because of the case reports in the literature identifying talc as the probable irritant in the formation of granulomas and adhesions in surgical patients, German [60] conducted experiments to study the relationship between talc and the etiology of granulomas in animals. Rabbits and guinea pigs were used, and talc of unknown composition was injected intraperitoneally (ip) or through laparotomy, with or without additional traumatization.

In one experiment, four female rabbits received ip injections of a talc suspension in physiological saline solution [60]. In two animals killed 18 and 20 hours later, aggregations of talc were found attached to the peritoneal wall and the peritoneal cavity yielded a small amount of a yellowish, cloudy liquid that contained macrophages that had engulfed minute talc crystals. No adhesions or signs of acute inflammation were found. The other two rabbits were killed after 4 weeks. No adhesions or exudates were found, but there were a few yellowish granulomas in the peritoneum and omentum. Microscopically, these granulomas were covered with intact layers of serosal cells and contained talc particles.

In other experiments German [60] introduced dry talc or talc suspension in saline into rabbits by laparotomy, in some of whose abdominal organs were also mechanically abraded. Dry talc produced more granulomas than that in suspension, and adhesions were found only in those animals whose organs had been abraded. Control animals whose viscera also had been abraded developed similar adhesions but no granulomas.

From these experiments, German [60] concluded that once talc was in the

WCD 001338

peritoneal cavity, it was immobilized and covered by serosal cells without the formation of an exudate or adhesion so long as there was no injury to the peritoneum. Adhesions developed only with traumatization and formation of fibrin. In such cases, talc was caught up in the fibrin and incorporated into the adhesions, thus increasing directly the bulk and density of granulomas in addition to inducing foreign body reactions. Both these results of the presence of talc increased the magnitude of fibrous tissue formation in granulomas and adhesions.

In another experiment, Odell et al [81] examined the formation of peritoneal adhesions and the effect of cortisone on these adhesions in adult white rats following injection of a talc suspension. The daily administration of 3 mg of cortisone intramuscularly (im) for 5-7 days prior to the ip injection of a talc-ink-saline suspension resulted in peritoneal adhesions which were few in number, thin, delicate and easily torn compared with those in a population of rats administered only the talc-ink-saline suspension. The authors observed no fibrin coagulation or deposition of masses of talc and exudate in the animals given the cortisone treatments similar to those found in the control animals. The authors speculated that the decrease in severity of adhesions may have resulted from a combination of an inhibition of the fibroblastic response to injury and the prevention of coagulation of exudate and fibrin by the cortisone. This work supports the conclusion of German [80] regarding adhesion formation and traumatization.

In addition to using rabbits, guinea pigs, and rats, Graham and Jenkins [82] also applied talcum powder to the peritoneal cavity and to skin wounds of kittens and mice. Fifty milligrams of talcum powder produced severe adhesions

WCD 001339

and marked granulomas within the peritoneal cavities of these animals within 6-9 weeks. When 10 mg of talcum powder was applied to skin wounds, fibrosis and granulomas similar to those seen in the peritoneal cavity developed, although the rabbits and mice were less severely affected than the kittens. This finding suggests that talc can produce skin granulomas, as has been reported by Tye et al (91).

(d) Distribution and elimination studies

Several authors have also reported studies (83,84,85) on the distribution and elimination of talc in animals exposed to talc by various routes. Wehner et al (83) used hamsters to determine the pulmonary deposition, translocation, and clearance of inhaled, neutron-activated cosmetic grade talc (5-6 u) in diameter, characterized in a previous experiment (75)). In this experiment, the researcher subjected 10-week-old hamsters to a single 2-hour exposure to neutron activated talc. Exposure was by inhalation only. During the next 4 months, groups of four hamsters each were killed and their bodies examined by gamma ray spectroscopy to locate the talc that remained in them.

The authors (83) found that 6-8% of the inhaled talc was deposited in the alveoli; the biologic half-life of talc deposited in the lung was 7-10 days, and it was essentially gone by the end of 4 months. No translocation to the liver, kidneys, ovaries, or other parts of the body from the gastrointestinal tract or lungs was found. The authors also mentioned briefly that small quantities of the radioactive label found in the urine probably leached from talc in the gastrointestinal tract.

In a similar study, Phillips et al (85) examined both the distribution and the absorption of tritiated pharmaceutical talc administered orally to

WCD 001340

rats, mice, and guinea pigs. Three male rats were each given single doses of
3130 50 mg of talc/kg body weight by oral intubation, three male rats were given
3131 oral doses of 50 mg/kg daily for 6 days, three female guinea pigs were each
3132 given single oral doses of 25 mg/kg, and four female mice were each given
3133 single oral doses of 40 mg/kg. Urine and feces were collected at 24-hour
3134 intervals, and all animals were killed after 10 days, except the mice which
3135 were killed after 6 or 24 hours. The results showed 95.6% and 94.4% recovery
3136 of the radioactive label from the feces of rats and guinea pigs, respectively,
3137 after 96 hours. In mice, virtually 100% of the radioactive label was found in
3139 either the gastrointestinal tract or in the feces, with <0.003% being detected
3140 in the rest of the body. Less than 2% of the radioactive label was found in
3141 the urine in any of the species examined, and the authors attributed the trace
3142 of the label that was found in the urine to probable contamination of the
3143 samples within the metabolism cages. The authors showed that talc
3144 administered orally was not absorbed from the gastrointestinal tract to any
3145 appreciable extent and that it was excreted almost entirely in the feces
3146 within 3-4 days.

3149 Wehner et al (84) studied the absorption of talc ingested by hamsters.
3150 Neutron-activated cosmetic talc (5-6u) in diameter characterized in a
3152 previous experiment (75), was suspended in physiologic saline solution. The
3153 talc suspension was administered by intubation to six 10-week-old female
3154 Syrian golden hamsters; four others received a suspension of nonirradiated
3155 talc, and four received no talc. After 24 hours, the hamsters were killed and
3157 various tissue samples were analyzed by gamma ray spectrometry.

3160 The data showed that, after 24 hours, approximately 75% of the radioactive

WCD 001341

label used as a tracer for talc was excreted in the feces, while approximately
3162 22% was found in the gastrointestinal tract (24). About 2% of the radioactive
3163 label was found in the carcasses, but the lungs, kidneys, and liver did not,
3164 differ significantly from those of the controls ($P>0.05$) in gamma ray counts.

3167 The results obtained by Wagner et al (24) using hamsters as test animals
3168 generally agree with those of Phillips et al (25), who used rats, mice, and
3169 guinea pigs. The intestinal absorption of talc was negligible (<2%) in all
3170 animals studied. Whether the small amounts of radioactivity found outside the
3172 gastrointestinal tract and feces represented intestinal absorption of traces
3173 of the damaged material was not determined. However, the authors' speculation
3175 that this may have been due to a leaching of the label from the talc seems
3177 reasonable.

3180 (e) Carcinogenicity, mutagenicity, teratogenicity, and reproduction
3181 studies

3184 Few studies have been located that examine the carcinogenic, mutagenic, or
3185 teratogenic potentials of talc, or the effects of talc on reproductive organs
3186 and processes. In 1976, Pott et al (26) reported on the tumorigenic effect of
3188 a variety of fibrous and granular dusts, including granular talc of unknown
3189 composition, introduced into the peritoneal cavities of rats as a suspension
3191 (12.5 mg/ml or 100 mg) in saline. The rats received the ip injections four
3192 times, at 1-week intervals. After injection, the animals were allowed to live
3193 out normal life spans or were killed whenever they became moribund. At
3194 necropsy, gross and microscopic examinations were performed on tumorous
3195 tissues.

3197 Visible amounts of talc dust were found within the abdomen of many rats

WCD 001342

[86]. On the average, the animals had a survival time of 602 days after injection. One rat out of 36 developed a mesothelioma after 587 days. The authors attributed the low frequency of tumor induction to the relatively nonfibrous nature of the talc.

In 1973, Smith [87] reported the effect of exposure to asbestos and other minerals, including a talc mixture containing 50% tremolite (characterized by the author as fibrous), 10% antigorite, and 5% chlorite, on male Golden Syrian hamsters. The talc was composed of 75% of the platy and 25% of the fibrous or rolled form. The average length and diameter of the fibrous particles were 5.7 and 1.6 μm, respectively, and the platy particles had a 2.0 μm diameter. Fifty hamsters each received a single intrapleural injection of 25 mg of the talc mixture. The animals were allowed to live out a normal life span or were killed whenever they became moribund. Gross and microscopic examinations were performed on the organs and tissues.

After 700 days, seven hamsters remained alive and were later killed for examination. Gross examination showed small depots of round and giant cells on the lung surface. Microscopic examination revealed no mesotheliomas. The author concluded that the talc mixture was not carcinogenic.

Wagner et al [70] also examined the incidence of tumors after exposure of rats to talc by inhalation, intrapleural injection, and ingestion. The talc used was of Italian origin with no asbestos fibers and <1% free silica. Groups of 24 animals were exposed by inhalation at a concentration of 10.6 mg/m³ for 6 months and for 12 months and examined by necropsy 10 days or 1 year after exposure. No malignant tumors were found in any of the animals exposed for either duration, although 1 adenoma was reported. A total of 7

WCD 001343

lung tumors were found in 48 animals exposed by inhalation to a known
3231 respiratory carcinogen which was used as a positive control. Feeding 32 rats
3233 100 mg of talc per day for 101 days resulted in one malignant tumor, a
3234 leiomyosarcoma, of the digestive tract. The authors noted three malignant
3236 tumors of the digestive tract and peritoneum in a control population of 126
3237 rats. The intrapleural injection of 48 rats with 20 mg of talc produced no
3238 mesotheliomas throughout the lifetime of these animals compared to 19
✓ 3239 mesotheliomas in 48 rats injected with a known carcinogen which was used as a
3240 positive control.

3242 Talc mutagenicity was evaluated for the US Food and Drug Administration
3243 (FDA) by a battery of screening tests, including a host-mediated assay,
3245 cytogenetic tests, and a dominant lethal test [86]. The characterization of
3246 the type of talc was not reported in this study. In the host-mediated assay,
3248 mice were given talc orally by intubation in doses of 30-5,000 mg/kg, either
3249 as a single dose or divided into five equal daily doses. Either
3251 dimethylnitrosamine or ethyl methane sulfonate was used as a positive control
3252 mutagen. The animals were injected ip with histidine-requiring mutants of
3253 Salmonella typhimurium and a diploid strain of Saccharomyces
3254 cerevisiae. After 3 hours, they were killed and the fluid from the
3255 peritoneal cavity was serially diluted and plated to determine mutation
3257 frequency. This test showed no significant increase in mutant colonies of
3258 Salmonella or recombinant colonies of Saccharomyces with talc, unlike the
3259 chemicals used as positive controls. In vitro mutagenicity testing of these
✓ 3261 microorganisms with talc also gave negative results.

3263 In the cytogenetic studies, the investigators [88] examined bone marrow

WCD 001344

cells of rats given talc orally at 30-5,000 mg/kg in one or five daily doses. The rats were killed 6-48 hours after the last dose was administered. Triethylenemelamine was used as the positive control substance. Human lung cell cultures treated with talc in vitro were also examined. Neither of these tests showed any significant difference from control values in the number and type of chromosomal aberrations.

In the dominant lethal study, talc was administered orally to groups of 10 male rats at 30, 300, 3,000 and 5,000 mg/kg in single or divided doses [86]. Triethylene melamine was administered ip to a positive control group of male rats. Following treatment, each male rat was bred to two virgin females each week for 7-8 weeks. The females were killed in the third week of gestation, at which time their ovaries were examined for corpora lutea, and their uteri for early and late fetal deaths and total implantations. Results were compared with those from a negative control group of male rats that had received only the saline vehicle, from the positive controls, and from historical controls involving about 100 females. Although significant differences from control values, in some instances appearing to be dose related, were found in some experimental groups during 1 or more weeks of breeding, these differences were not consistent and showed no overall dose-response relationship or time-trend patterns. Therefore, talc was considered nonmutagenic in the dominant lethal assay system at the doses tested.

The teratogenic potential of talc in corn oil was evaluated for the FDA with screening tests on rabbits, mice, rats, and hamsters [87]. The talc was administered in corn oil and was not characterized in this study. Dutch-belted rabbits received talc by intubation at 2.5-900 mg/kg/day on days 6-18 of

WCD 001345

gestation, and fetuses were examined following cesarean section on day 29.
Albino CD-1 mice and Wistar rats were given talc in oral doses of 16-1,600
mg/kg/day on days 6-15 of gestation; mouse fetuses were examined on day 17 and
rat fetuses on day 20. Golden hamsters received talc orally at 12-1,200
mg/kg/day on days 6-10 of gestation and fetuses were examined on day 14. As a
positive control, rabbits were given 2.5 mg/kg of 6-aminonicotinamide on day 6
and other species received aspirin in daily doses of 150 or 250 mg/kg. The
animals were observed throughout gestation for changes in food consumption and
weight. At the end of the gestation period, their ovaries were examined for
numbers of corpora lutea, and their uteri for implantation and resorption
sites and for live or dead fetuses. Living fetuses were weighed, and live
rabbit fetuses were incubated for 24 hours to determine survival. The fetuses
of all species were examined for external and visceral abnormalities and were
cleared for determination of skeletal abnormalities.

In all four species, talc at the doses tested had no effect on implantation, on maternal, or on fetal survival [69]. The numbers and types of fetal abnormalities did not differ from those occurring spontaneously in controls treated only with the corn oil vehicle.

No studies showing reproductive effects from talc exposure have been found.

Correlation of Exposure and Effect

There are many reports concerning the toxicity of talc but most are inadequate for the purposes of correlating exposure and effect. Available literature does not adequately characterize talc and often lacks such

WCD 001346

information on particle size, particle morphology and precise mineral composition. Interpretation of many biologic studies concerning talc exposure is further complicated by the presence of asbestos and free silica among the minerals associated with talc. Since this document recommends a workplace standard for airborne talc dust that contains <50 (a)/o free silica and no asbestos, studies concerned with talc containing asbestos or free silica will not be addressed in this attempt to correlate the effects of talc with exposure. In many studies, environmental concentrations of talc are not reported or, if reported, may have been determined as number of particles per volume of air rather than as mass respirable dust. An accurate, universally applicable method for converting measurements of particle counts to mass respirable dust does not exist. In addition, estimates of previous exposures in most papers were based on recent measurements and anecdotal information, and thus, may not accurately reflect the actual exposure that occurred.

Despite the shortcomings of the literature describing effects of exposure to talc, it has been established that inhalation of talc not containing asbestos and with <1% free silica has produced pneumoconiosis in workers manifested as clinical symptoms of respiratory disease, chest X-ray film abnormalities, and decreases in pulmonary function measurements. This triad of signs and symptoms seen in pneumoconiosis resulting from occupational exposure to talc does not consistently occur together at a given exposure level in individual workers. Smoking and concomitant respiratory diseases, for example, will impose an additional challenge that modifies the course of the disease.

Clinical symptoms of respiratory disease, one of three health effects

WCD 001347

associated with talc exposure, has been described by a number of authors
3360 [31,33,68]. Millman [31] described a case of a cosmetic talc worker exposed to
3361 talc for 24 years. The worker developed chest pains and general weakness,
3362 which, together with X-ray film findings, enabled the author to conclude that
3363 the worker was suffering from pneumoconiosis resulting from his exposure to
3364 talc. At the time of diagnosis, sampling of the area where this man worked
3366 revealed dust concentrations in the general room air to be 15.9 mppcf with a
3367 concentration of 236 mppcf during the process of filling the machine that
3368 mixed the various ingredients used in the talcum powder. The concentration of
3369 talc in the breathing zone of the worker was not reported.
3371 Two recent studies have reported findings of symptoms of respiratory
3372 disease among workers exposed to known levels of talc measured as mass
3373 respirable concentrations [17,68]. Fine et al [17] reported on a study of
3374 rubber workers exposed for an average of 8.9 years at concentrations measured
3375 at the time of the survey as 0.47-3.55 mg/cu m. The authors stated that
3377 exposures over the past 20 years had probably not changed substantially. A
3378 statistically significant increase in symptoms of bronchitis and chronic
3379 obstructive lung disease was found among talc workers who smoked compared to a
3380 control population of rubber workers who also smoked but were not exposed to
3381 talc. A statistically significant increase in these symptoms was not found in
3382 a similar comparison with nonsmoking talc and rubber workers. Wegman et al
3383 [68] reported abnormal lung sounds in 12 of 117 workers (10%) exposed at
3384 concentrations of talc measured at the time of the survey as <2 mg/cu m. In 4
3385 of these workers, the lung sounds were categorized as minimal and were
3386 considered by the authors to be transitory. These authors stated that

WCD 001348

previous exposure levels were probably much higher.

X-ray film abnormalities are another health effect that has also been associated with talc exposure by various authors [65,17,32,60]. Rubino et al [60] reported X-ray film abnormalities which were classified according to the ILO system among talc millers in Italy. X-ray film abnormalities were not observed for any of the workers exposed for <80 appf-years however, 3 of 11 workers (21%) exposed in the range of 80-320 appf-years showed initial or more advanced X-ray film changes (0/1 or greater). In the group with exposure levels >320 appf-years, 9 workers (82%) had at least initial x-ray film signs of pneumoconiosis and 2 of 11 workers (18%) in this group, exposed for an average of 22 years at an average concentration of 11 appf, had X-ray films definitely consistent with pneumoconiosis (1/1 or greater).

Fristedt et al [32] described five cases of pneumoconiosis found in rubber manufacturing plant in Sweden; the cases were diagnosed by X-ray films. The levels of exposure of the workers at the time of the study ranged from 10-121 appf and the workers were exposed for an average of 31.2 years. Mild, or stage I talcosis was found in four of five workers and the remaining worker suffered from stage III pneumoconiosis and rheumatoid arthritis (Caplan's Syndrome). The increase in severity in this worker suggested to the authors a possible increase in susceptibility to talcosis among workers with rheumatoid arthritis.

Only two studies have reported X-ray film examinations among workers exposed to levels of talc measured as mass respirable concentrations. Fine et al [17] reported on a study of rubber workers exposed to talc for an average of 8.9 years at concentrations measured during the survey as ranging from

WCD 001349

0.47-3.55 mg/cu m. The authors stated that none of these workers showed X-ray film abnormalities definitely consistent with pneumoconiosis but it was not reported whether initial X-ray film signs of pneumoconiosis were found in any of these workers. Wagman et al [68] also reported X-ray film findings among talc workers. Average current exposure levels were <2 mg/cu m, although the authors noted that previous exposure levels were probably higher than current levels and it was therefore not possible to estimate cumulative exposures. Forty six percent of the workers had small round or irregular opacities in the lungs indicative of pneumoconiosis, and 18% of these workers had X-ray films definitely consistent with pneumoconiosis (equal to or greater than 1/1 according to the ILO system).

A third health effect, decreased measurements of pulmonary function in workers exposed to talc, has also reported by a number of authors [33,32,17,68]. Fristedt et al [32] reported that lung function was not affected in four of five workers with pneumoconiosis exposed to talc for an average of 31.2 years at concentrations ranging from 10 to 121 mppcf. The lung function of the remaining worker was "slightly impaired." The specific pulmonary function measurements were not reported. Scansetti et al [33] noted the results of lung function measurements among workers with X-ray film abnormalities who were exposed to unspecified levels of talc revealed no alterations worth mentioning. Decreases in FEV 1 have been reported in two recent studies that have examined the degree of pulmonary function changes in response to talc exposure through the use of multiple regression analysis [17,68]. A small decrease in FEV 1 was reported among smokers (97.3% of predicted) and no change was reported in nonsmokers exposed to talc at

WCD 001350

concentrations measured between 1 and 2 mg/cu m at the time of the study [68].
The author of this study suggested an interaction of cigarette smoking and talc exposure which resulted in the larger change in FEV 1 than would have been expected due to cigarette smoking alone. Fine et al [17] also reported a decrease of FEV 1 in talc workers exposed for more than 10 years at concentrations of talc ranging from 0.47-3.55 mg/cu m. Using a multiple regression model that corrected for smoking history, height and age, the authors concluded that each year of exposure to talc dust at these levels reduced FEV 1 by 36 ml.

The effects of experimental exposure of animals by inhalation to known quantities of respirable talc dust has been reported [75,76]. Wehner et al [75] exposed hamsters to talc concentrations of 27.4 mg/cu m for 30 days or to 37.1 mg/cu m for 300 days or until death. The authors did not find a dose-related increase in the incidence of pulmonary lesions, but females exposed at the highest concentration experienced a significant increase in the incidence of focal alveolar hyperplasia, histiocytosis, and interstitial pneumonia. Wagner et al [76] exposed rats to talc by inhalation at a level of 10.0 mg/cu m for either 3 months, 6 months, or 12 months. All exposed animals had mean fibrosis scores greater than those of control groups, and the severity of fibrosis increased with duration of exposure. The severity of fibrosis also continued to increase after the cessation of exposure as evidenced by the greater degree of fibrosis found among the groups of animals examined 1 year after the final exposure as compared to those examined 10 days after the final exposure.

The exposure of animals to talc by inhalation is consistent with exposure

WCD 001351

and effect information from human studies. All of the signs and symptoms resulting from exposure to talc, although presented discretely in this correlation of exposure and effect, are aspects of the same disease syndrome. The chest X-ray film abnormalities, the decrease of lung function measurements and other clinical signs and symptoms resulting from exposure to talc are progressive and are influenced by extent of dust exposure, age, smoking habits and other concomitant diseases.

Although it may be argued reasonably that the triad of adverse effects noted from exposure to talc should follow a normal progression from symptoms of respiratory irritation to architectural changes in the respiratory system (as can be seen in X-ray films) to pulmonary function decreases, data confirming the occurrence of such a progression are not available. In fact, the information that does exist concerning a progression within the triad is apparently contradictory, perhaps as a result of differing methods of observation and measurement, as well as differing individual susceptibility.

When analyzed together, the effects of talc exposure constitute a greater hazard than exposure to a nuisance dust. Studies suggest that exposure to talc for periods longer than ten years at concentrations that might have been <1 mg/m³ [17] or 1 mppcf for 22 years [65], has caused at least initial signs or symptoms of pneumoconiosis. There is no agreement on the estimates of exposure and the biologic significance of the effects reported as initial signs or symptoms of pneumoconiosis; however, NIOSH believes that there is sufficient evidence that long-term low-level exposure to talc can cause adverse health effects in workers.

WCD 001352

Carcinogenicity, Mutagenicity, Teratogenicity, and Effects on Reproduction

No studies demonstrating that talc free of asbestos minerals produced cancer or tumors in humans or animals have been found. However, a recent Russian paper [64] has concluded that talc dust, even though it contains no fibrous components, is an industrial carcinogen. The data to support such a conclusion are not provided in the paper, however.

One epidemiologic study showed no significant increase in incidence of deaths from cancer of the lung, larynx, pleural esophagus, intestine, liver, stomach, or in all other sites in workers exposed at 0.6-79% upper, and in the corresponding controls [34]. Another study showed that the incidence of deaths from respiratory cancer was greater in workers exposed to talc free of asbestos minerals than in the state and national mortality statistics; however, the workers exposed to talc were also exposed to radioactive materials (radon-daughters) in this study. Two studies [56,76] suggested that talc free of asbestos minerals might induce tumors in animals. Pott et al [86] reported that one of 36 rats developed a mesothelioma after 587 days following 4 intratracheal injections of 25 mg of talc suspension into each animal. Wagner et al [76] found no mesotheliomas in 48 rats injected intrapleurally with 20 mg of talc. They also found no malignant tumors in 48 rats exposed by inhalation to 10.0 mg/cu m for up to 12 months. Feeding of 32 rats 100 mg of talc per day for 101 days resulted in one tumor, a leiomyosarcoma, of the digestive tract.

It appears from the reported data that exposure to talc free of asbestos minerals has not demonstrated unequivocally carcinogenic or tumorgenic effects in humans or animals. No studies have been located demonstrating that talc

WCD 001353

characterized as free of asbestos minerals produces mutagenic or teratogenic
3543 effects in humans or animals.

3547 Summary of Tables of Exposure and Effect

3550 The effects of exposure to talc presented in Chapter III are summarized in
3551 Tables III-8 and III-9.

WCD 001354

TABLE III-8

SUMMARY OF EFFECTS ON HUMANS FROM EXPOSURE TO TALC NOT CONTAINING ASBESTOS OR >1% FREE SILICA

Talc Type*	Average Dust Levels	Average Years Exposed	Number of Workers	X-ray Film Abnormalities** (%)	Respiratory Disease*** (%)	Selected Pulmonary Function Measurements	References
IGT	.47-3.9 mg/cu m	8.9	80	0	31	FEV 1 significantly reduced in workers employed more than 10 years	[17]
IGT	1.5 -1.9 mg/cu m****	8.5	117	46	10	FEV 1 slightly reduced in smokers	[68]
CGT	6.1 mppcf	7.5	8	0	No Data	No data	[65]
CGT	8.5 mppcf	12.5	11	27	"	"	[65]
CGT	11.3 mppcf	21.8	13	69	"	"	[65]
CGT	14.6 mppcf	23.7	11	82	"	"	[65]
IGT	49.9 mppcf****	30.2	50	100	100	Lung function reduced in one worker	[32]
CGT	15.9 mppcf****	24	1	100	100		[90]

*IGT - Industrial Grade Talc; CGT - Cosmetic Grade Talc
**X-ray film findings that are consistent with, indicative of, suggestive of, or the initial stages of pneumoconiosis (author's evaluation)
***Workers having at least one of the following: cough, phlegm, breathing difficulties, wheezing
****Current exposure levels, not necessarily indicative of previous exposure levels
#Only workers diagnosed as having pneumoconiosis were examined

WCD 001355

TABLE VII-9

EFFECTS ON ANIMALS EXPOSED TO TALC BY INHALATION

Talc Type	Species and Number	Concentration (mg/cu m)	Length of Exposure	Approx Cumulative Exposure (mg/cu m-hr)	Effects	Reference
Pharmaceutical*	Rats 7 M	23-383**	6 hr/d 6 d/wk 9 mo	280,000	Emphysema, pleural plaques, thickening of pulmonary arterial walls, granulomas	[77]
"	"	23-383**	6 hr/d 6 d/wk 6 mo	190,000	Thickening of pulmonary arterial walls, granulomas, severe inflammation	[77]
"	"	23-383**	6 hr/d 6 d/wk 3 mo	94,000	Mucous membrane inflammation, macrophage infiltration of alveolar lumina	[77]
"	"	23-383**	6 hr/d 6 d/wk 2 wk	14,000	Increased mucus in upper respiratory tract	[77]
"	"	23-383**	6 hr/d 6 d/wk 1 wk	7,200	No changes reported	[77]
Pharmaceutical*	Hamsters 48 M	8	2.5 hr/d 300 d	6,000	"	[75]
"	Hamsters 48 F	8	2.5 hr/d 300 d	6,000	Increased frequency of interstitial pneumonia and alveolar cell hyperplasia	[75]

WCD 001356

TABLE III-9 (CONTINUED)

EFFECTS ON ANIMALS EXPOSED TO TALC BY INHALATION

Talc Type	Species and Number	Concentration (mg/cu m)	Length of Exposure	Approx Cumulative Exposure (mg/cu m-hr)	Effects	Reference
Pharmaceutical	Hamsters 49 M	8	0.5 hr/d 300 d	1,200	No changes reported	[75]
	Hamsters 50 F	8	0.5 hr/d 300 d	1,200	Increased frequency of alveolar hyperplasia and alveolar histiocytosis	[75]
"	Hamsters 48 M	8	2.5 hr/d 30 d	600	No changes reported	[75]
"	Hamsters 50 F	8	2.5 hr/d 30 d	600	"	[75]
"	Hamsters 50 M	8	0.5 hr/d 30 d	120	"	[75]
"	Hamsters 49 F	8	0.5 hr/d 30 d	120	"	[75]
"	Hamsters 49 M	8	0.05 hr/d 30 d	12	"	[75]
"	Hamsters 47 F	8	0.05 hr/d 30 d	12	"	[75]

*Polish pharmaceutical talc of the type used in hospitals for preparation of surgical gloves and related uses

**Median concentration of 200 mg/cu m

#High purity cosmetic talc powder sold in United States. Over 95% (W/W) platy talc with trace quantities of carbonates, platy chlorite, and rutile.

WCD 001357

Talc is a crystalline mineral that can become airborne when mined or milled for commercial use. The sampling and analytical methods in use measure dust counts, fiber counts, mass concentrations, and analyze particle composition of the dust. The most commonly used methods are discussed below along with available information on worker exposure and engineering control measures.

Dust Measurement

Many comprehensive reviews are available on the subject of dust sampling [90,92,93, 94,95,96,97,98,99]. The basic principles of the applicable methods are briefly discussed here.

(a) Counting Procedures

Microscopic counting of dust particles collected by dry or wet impingement has been used for many years to evaluate exposure to dust. Dry impaction devices, such as the konimeter [99], the Owens jet dust sampler [99], and the Bausch and Lomb dust counter [100], were among the earliest dust sampling devices developed in the 1920's and 1930's. They were widely used in South Africa and England for the sampling of coal dust. These devices use a piston pump to draw a single air sample of 5-50 ml through an orifice, creating a high velocity jet for impaction of the particles on a glass slide or disc. A microscope is frequently positioned to observe the target of impaction in the sampling device, for direct counting and sizing of the particles collected. Collection efficiency is satisfactory down to the limit of resolution of the

WCD 001358

light microscope. However, interpretation of the results may be difficult because particles may be fractured by the high velocity jet impaction.

In the 1940's, multistage jet impactors [101,102,103] were developed that could collect particles from larger volumes of air and separate them into fractions of different size ranges. Air was drawn through a series of jets of progressively smaller sizes, which resulted in higher efficiency of impaction for successively smaller particles. After calibration, the particle size distribution was determined by counting the particles deposited on each stage. One investigator [103] found that a four-stage impactor collected 1.5 tube particles of unit density with an efficiency approaching 100% at the last stage. The agglomerated particles were not shattered because they were collected in the initial stages at a relatively low impaction velocity. These dry impingement methods could have been used to sample for talc particles, but no data have been found that indicate they were. Even in general dust sampling, these devices are seldom used currently and the Bausch and Lomb Dust Counter is no longer commercially available [104].

Wet impingement methods are more widely used than dry impingement methods in the collection of dust particles. In a wet impinger, impingement takes place through a jet submerged in a liquid medium, usually water or alcohol. Greenburg and Smith [105] developed the earliest wet impinger in 1922. A modified version of this instrument [93,97] was intended to be operated at 1 cu ft/minute with 75 ml of liquid and developed an impingement velocity of about 100 m/second. A smaller midget impinger containing 10 ml of liquid and operating at 0.1 cu ft/minute with an impingement velocity of 70 m/second was developed in 1937 [95]. The efficiency and application of both models of wet

WCD 001359

impinger have been discussed by several investigators [106,96,97]. The
3781 smallest size of dust particles that can be identified after collection by
3782 these methods depends on the sampling procedure and the resolution of the
3784 microscope. With a 90X objective lens, the lower limit of detection is
3787 approximately 0.7 cubic [106].

3789 Because the lower limit of detection varied with different combinations of
3790 sampling and counting techniques, a standardized method [107,108] was devised
3791 to facilitate comparison of the results obtained by different operators. With
3793 this standardized method, air is collected in a standard impinger at a
3794 flowrate of 1 cu ft/minute, or in a midget impinger at 0.1 cu ft/minute, and a
3795 90X objective is used for counting. This dust-counting method detects only
3797 those distinguishable particles that are collected in the liquid and that
3798 settle to the bottom of a counting cell. The resulting count is a measure of
3800 overall dust-particle concentration rather than of the quantity of a specific
3802 dust, such as talc. Nevertheless, total dust concentration has been a useful
3803 measure of airborne particles in the workplace and of the relative
3805 effectiveness of various control methods. According to the available data
3806 [71], great improvements in the working environment of talc-processing
3808 facilities were achieved on the basis of counts by this method. While such
3810 particle counting may have been adequate in dusty workplaces with high
3811 exposure concentrations before 1950, efforts to further reduce the incidence
3812 of pneumoconiosis and to define more clearly the relationship between exposure
3813 and its biologic effects have led to the development of more refined dust-
3815 measurement techniques.

3818 (b) Respirable Dust Mass Measurement

WCD 001360

Since pneumoconiosis arises from excessive retention of relatively large amounts of dust in the lungs, measurement of the portion capable of penetrating into the alveoli should permit better analysis of concentration-effect relationships than measurement of total dust in the air, and thus, should be an especially pertinent measurement for evaluation of the respiratory health hazard. The British Medical Research Council used the term respirable dust for the dust that reached the alveoli [109], while the US Atomic Energy Commission, in 1961, used the term for dust that penetrated to the nonciliated part of the lungs [2,110]. In a more general definition, particles with an equivalent aerodynamic diameter of 1-5 μm or less are regarded as respirable dust. To determine the fraction of total dust which is respirable, a device that simulates the selectivity of the lungs is necessary, and for this a two-stage sampling device is normally used. The first stage collects the larger particles that would usually deposit in the upper respiratory tract and the second stage collects those that are small enough to penetrate to the pulmonary air spaces. Hatch and Nesson [111], in 1948, suggested the use of a two-stage sampler, and several investigators have published design or performance specifications for such devices [112,113,109]. Lippmann [110] recently compiled a list of two-stage respirable dust samplers developed by various investigators. Horizontal elutriators and cyclones have been the most widely used devices for the first stage, while the second stage generally is a filter. A commonly used sampler is one that consists of a 10-mm nylon cyclone separator and a 37-mm diameter membrane filter.

Total-dust sampling has also been used to evaluate occupational exposure to dust. Generally, the weight of the dust particles collected on a filter is

WCD 001361

used to calculate mass concentration. This method is simple, but a few large particles could contribute a disproportionately large part to the total weight determined, obscuring a large number of the smaller particles that present a greater health hazard.

Of the aforementioned dust counting and mass measurement methods, respirable dust sampling gives the best indication of the hazards to respiratory systems from inhaled dust. Therefore, NIOSH recommends respirable dust sampling to evaluate workers' exposure to talc. Although the dust samples collected would contain other airborne particles as well, in a workplace processing (mining, milling, and using) talc, it is expected that most of the airborne dust particles would come from the talc powder processed, handled, used or stored. Samples should be taken from the employee's breathing zone over a full workshift to measure more closely the total exposure. The recommended method of dust collection is presented in Appendix I.

Dust Analysis and Fiber Count

Because talc deposits are associated with many different minerals, such as tremolite, anthophyllite and actinolite, and can exist in various metamorphic forms, hardly any ore contains only pure talc [1]. Most of the ores mined contain only 15-60% pure talc [22]. The impurities are generally silicates or carbonates, which are predominately nonfibrous, but may also be in fibrous form. They do not usually interfere with the intended uses of the talc, and are usually not removed from talc products. To evaluate the health hazards of exposure to talc dust, it is important to analyze its mineral composition and

WCD 001362

WCD 001363

morphology, as some of the impurities may also cause health hazards. Of the various impurities which are common in talc deposits, two, crystalline silica and asbestos fibers have significant adverse health effects. NIOSH has prepared criteria documents for asbestos [9,10], and the methods of sampling and analysis recommended in these documents can be used to evaluate workers' exposure.

The X-ray diffraction method given in the NIOSH Manual of Analytical Methods [114], or other methods equivalent in precision and sensitivity, should be used to analyze for crystalline silica in a talc dust sample. In the X-ray diffraction method, respirable dust is collected on a low-ash polyvinyl chloride filter and then redeposited on a silver membrane filter that is analyzed by X-ray diffraction analysis. As little as 5 (μg) of each free silica polymorph in a sample can be detected using this method.

In the original asbestos criteria document [9] and the revised recommended asbestos standard [10], NIOSH recommends optical counting of fibers for the evaluation of worker exposure to asbestos. Fibers are collected from air on a membrane filter in an open-face filter holder. A portion of the filter is mounted on a slide and then rendered transparent for counting with phase contrast microscopy at 400-450X magnification. Particles longer than 5 (μm) with a length-to-diameter ratio of 3:1 or greater are counted as fibers. Because resolution of the light microscope is limited and because of the imposed definition of a fiber, the fiber count concentration is only a relative indicator of fiber exposure.

This counting method takes into account all particles fitting the definition of a fiber but does not positively identify the mineral species of

the fiber. In a situation where fibrous and nonfibrous dusts of several mineral species may be present at the same time, such as in a talc milling plant, optical counting will not give a good estimate of asbestos fiber concentration in air. For instance, Soundy et al [20], using scanning electron microscopy, found that the fibers counted in talc samples using phase contrast microscopy often were talc shard and rolled talc particles rather than asbestos fibers. Of course, the optical counting method will be suitable if the talc powder used in a plant is known to contain asbestos fibers but no other mineral fibers. However, such occasions are rare and a more sophisticated analytical method will be needed to determine asbestos fiber concentration in a talc dust sample.

To identify fibrous minerals in a sample of talc, polarized light microscopy with a dispersion staining objective lens is often used [11]. In this technique, the fibers are counted in a dispersion liquid with a refractive index similar to that of the fibers but with a steeper dispersion curve. A central stop is most commonly used in the back focal plane of the objective lens to allow complementary color to appear around the particle boundaries. Dispersion staining imparts characteristic colors to each asbestos fiber, facilitating detection and identification. Fibers with dimensions of 0.2x3 μm or larger have been detected in a sample containing more than 0.01% of fibers by weight. This technique is obviously limited by the resolution of the light microscope, which is about 0.2 μm with an oil immersion lens. Because of this resolution limitation and of possible interferences from other minerals, optical microscopy is useful only for preliminary analysis. Also, it is unknown whether the sample-counting

WCD 001364

technique for bulk powder samples can be applied to airborne dust samples collected on a filter.

X-ray diffractometry is a standard mineralogic technique used in the analysis of solid crystals and has been widely used to analyze talc samples. Because of the characteristic diffraction of X-ray beams by talc and its associated mineral crystals, qualitative determination of the components of talc samples can be made. For quantitative analysis, a calibration standard is needed. In a review of current techniques for analysis of fibers in talc, Langer et al [115] pointed out the importance of selecting a mineral standard of high purity, of proper sample preparation, and of appropriate dilution of the standard matrix. A number of excellent books and reviews [116,117,118,119,120] have discussed X-ray diffractometry in detail.

Using X-ray diffraction to determine the asbestos content of talc samples, Nenadic and Crable [121,122] detected 1-5 mg of talc and 1-5 mg of tremolite in samples collected on a membrane filter and analyzed with external standard procedures. For bulk powder samples, internal standard procedures permit accurate analysis of samples containing 1% or more of talc or tremolite by weight. Using the step-scanning mode of operation, Kohl and Langer [123] were able to detect anthophyllite at a concentration by weight of 2%, chrysotile at 0.25%, and tremolite at 0.1% in a binary matrix with talc. Schulz [124], using the same procedures, was able to detect amphiboles at <0.5% by weight in a talc matrix. Since X-ray diffractometry reveals only the crystalline structure of a mineral, the shapes of the particles cannot be determined by this method. Thus, it cannot be determined whether the tremolite or anthophyllite identified exists in a fibrous form or not. It is also possible

WCD 001365

to miss amphiboles that are present in low concentrations. Birks et al [125]
3989 studied the quantitative analysis of airborne asbestos fibers using X-ray
3990 diffraction analysis. A specially designed apparatus containing two X-ray
3991 detectors was used, and the fibers were aligned in an electrostatic field to
3992 enhance diffraction intensity. A detection limit of 0.2 fo/g for chrysotile
3993 was reported, but the technique has not been applied to actual environmental
3994 samples.

3996 The method recommended by the Cosmetic, Toiletry, and Fragrance
3996 Association [126] combines X-ray diffractometry, dispersion staining
3997 techniques, and morphologic characterization to confirm the presence of
3999 fibrous amphiboles in talcum powder through successive elimination processes.
4000 First, X-ray diffractometry is used to determine the presence of amphiboles,
4001 then the dispersion staining procedure identifies those fibrous amphiboles
4002 conforming to certain morphologic definitions. To minimize interferences from
4004 carbonates in the sample during dispersion staining, the sample is first
4005 leached with hydrochloric acid. This succession of analytical procedures
4006 permits a quick and positive determination of the presence of fibrous
4007 amphiboles in a powder sample, but it cannot differentiate among the
4008 amphibole species. This technique is only applicable for qualitative
4009 analysis, and procedures must be developed for detecting and estimating
4010 amphibole minerals in dust collected from the air.

4013 Differential thermal analysis is another technique that can be used to
4014 detect asbestos in a mineral sample [124]. This technique is based on the
4016 characteristic endothermic or exothermic reactions caused by dehydration or
4017 formation of new phases when the crystals are heated. Thermograms of talc and

WCD 001366

chrysotile have peaks at different temperatures, but amphibole asbestos has peaks indistinguishable from those of talc. Therefore, only chrysotile in a talc sample can be detected by this method, down to a lower limit of 1% chrysotile in a mixture.

Besides detection of asbestos material, the morphology of dust particles must be examined to determine whether true asbestos fibers are present in a sample. Transmission electron microscopy, at a magnification of 1,500-40,000X, can be used to compare the morphologic characteristics of all particles. Such characteristics as length-to-width ratio, electron diffraction contrast figures, cleavage characteristics, and edge characteristics of fibers in a talc sample can be identified. Langer et al [115] reported that amphibole and chrysotile fibers can be easily differentiated by this technique, but that amphibole fibers may be difficult to distinguish from talc fibers.

Transmission electron microscopy can be used to observe the diffraction image caused by scattered electrons [115,127]. A specific technique, called selected area electron diffraction, is based on a principle similar to X-ray diffraction, except that an electron beam from a transmission electron microscope is used and only a small area of the sample is examined at a time. Thus, single fibers can be examined and the interspacing dimensions and angular characteristics are determined from diffraction patterns, permitting identification of chrysotile and amphibole fibers. However, the particular species within the amphibole group still cannot be identified. A goniometer is often required to place the fiber into a favorable orientation for examination. The higher the energy in the electron beam, the thicker the fiber that can be examined; however, thin fibers may not generate enough

WCD 001367

interferences to produce a diffraction pattern. Despite these shortcomings,
4052 the use of transmission electron microscopy with selective area electron
4053 diffraction can provide definitive identification of asbestos fibers.

4056 For a more sophisticated identification of the fibers in a talc sample,
4057 electron beam microchemical analysis, also called electron microprobe
4058 technique, can be used. Electron beam microchemical analysis is based on the
4060 concept that X-rays characteristic of an element are produced when the element
4061 is bombarded with high energy electrons. Either of two probe techniques,
4063 wavelength dispersive or energy dispersive X-ray analysis, is used. The
4064 latter is preferred because it requires less time for an analysis [115]. The
4065 relative ratios of all elements with atomic numbers greater than 10 can be
4067 determined with this technique, and thus also the chemical composition of a
4068 fiber or particle. Therefore, in addition to the morphologic information
4069 derived from transmission or scanning electron microscopy and from electron
4070 diffraction patterns, the mineral species of a fiber can also be specifically
4071 identified with the electron microprobe technique. That is, tremolite
4073 asbestos and anthophyllite asbestos can be distinguished from one another
4074 using this method.

4076 Identification and quantification of fibers in airborne dust samples
4077 requires special preparation procedures to minimize fiber loss and facilitate
4078 analysis by electron diffraction and microchemical techniques. The US
4079 Environmental Protection Agency (EPA) [12] has recently published such
4080 techniques for use with polycarbonate filters. Zumwalde and Dement [120] have
4081 also described procedures for preparing membrane filters. The procedures for
4083 use with membrane filters are preferred for sampling of occupational talc

WCD 001368

exposures since counting of fibers by the standard phase contrast method for asbestos can be done on the same filter. Briefly, the dust sample collected on a membrane filter is fused with acetone to produce a smooth surface that is vacuum-coated with carbon. The sample is then transferred to an electron microscope grid by an acetone washing procedure. Other procedures for sample preparation have been reviewed by Zumwalde and Dement [128].

Electron microscopic analysis techniques, which include electron diffraction, are time consuming and require expensive equipment and special training. However, these techniques provide the most definitive results with respect to fiber detection and identification.

There is no simple and satisfactory method for analysis of a talc sample collected either from workroom air or from bulk powders. Some methods, such as X-ray diffraction and differential thermal analysis, identify the mineral content but not the shape of the particles. Other methods, such as optical microscopy and transmission electron microscopy, will reveal the shape of a particle but not the nature of its mineral content. Some combinations of methods, such as that suggested by the Cosmetic, Toiletry, and Fragrance Association [126], are only suitable for qualitative identification. Only the use of transmission electron microscopy with selected area electron diffraction analysis will identify fibrous amphiboles. If further analysis is needed, the electron microprobe technique can be used to differentiate between tremolite fibers and anthophyllite fibers. However, these techniques are quite time consuming to perform and require expensive equipment and highly trained personnel. Therefore, NIOSH recommends the following sampling and analysis scheme for determining worker exposure to talc and its associated

WCD 001369

minerals at minimum cost.

Samples of respirable dust should be collected to determine their mass concentration in a talc workplace. These samples should also be analyzed for quartz content to estimate the concentration of free silica in workroom air. To determine whether a worker is also exposed to asbestos fibers, periodic examination of the bulk talc powder should be done first. Transmission electron microscopy with selected area electron diffraction analysis should be used to determine asbestos content in bulk samples. If asbestos fibers are present in the talc powder, then airborne dust samples should be collected in accordance with the method outlined in the revised recommended standard on asbestos. If the TWA fiber count so determined is higher than the recommended limit of 0.1 fibers/cc, then further identification of the fibers by electron microscopy will be needed to ascertain if the limit is actually being exceeded. This should be done by transmission electron microscopy with selected area electron diffraction analysis. The diffraction patterns of the fibers identified in the electron micrograph should be examined to determine the content of asbestos amphiboles. From this data, the true asbestos fiber counts in a dust sample collected from the talc work environment can be determined.

Environmental Concentrations

There have been many reports in the past 30-40 years on pneumoconiosis due to occupational exposure to talc (see Chapter III). Most of these investigations have reported exposure concentrations in addition to observed or measured physiologic changes in workers who had worked in talc mines.

WCD 001370

mills, and related plants. It is possible from these reports to document the results of various engineering controls initiated to reduce occupational exposure to talc.

Dreessen [36], in 1933, reported that drillers using jackhammers in a mining and milling plant, were exposed to talc that contained tremolite at an average concentration of 1,440 mppcf, and that millers in the same plant were exposed at about 52 mppcf. Sixty-eight percent of the talc particles were <2 fuls in diameter. Dreessen and DallaValle [37] investigated two Georgia mines and mills in 1935 and found that drillers in the mines were exposed at 858 mppcf and muckers at 32 mppcf. In the milling plants, the packermen had the highest exposure at 1,672 mppcf, followed by sawyers (blockers, slabmen, and pantlmen) at 324 mppcf.

The Division of Industrial Hygiene of the New York State Labor Department has conducted extensive surveys of talc mines and mills within the state since the 1930's, and the data collected offer one of the best records of improvements in the work environment of talc operations. The first study was reported by Siegal and associates [38,129] in 1949 on plants located in St. Lawrence County. Midget impingers were used to collect air samples, and average concentrations of 1,350 mppcf in areas of drilling, 1,290 mppcf where stoping was in progress, and 33 mppcf for sacking were found in the mines. In the milling plants, workers who performed bagging were exposed at 163 mppcf and those involved in manual bagging were exposed at 215 mppcf; exposures at other operations ranged between 46 and 93 mppcf. A follow-up study reported by Kleinfeld [39] in 1955 found a dramatic improvement in the workplace environment. In the mines, average concentrations were only 3 mppcf for

WCD 001371

drillers, 4 mppcf for muckers, and 11-37 mppcf for various operators in the milling plants. These improvements were brought about by a number of changes, including wet drilling, mine ventilation, enclosure of the elevators and chutes, installation of automatic bagging machines, conveyor car loading, discontinuance of the blow room, and provision of local exhaust ventilation. Changes of similar magnitude were also seen in mines and milling plants in Lewis County, New York during the same period [71]. These data are presented in Table IV-1. It should be pointed out that the pre-1945 data, as reported by Kleinfeld et al [39], differ from those reported by Siegel et al [38,120], The latter reports included more data but reported only the average values.

WCD 001372

.4202 TABLE IV-1

4204 COMPARISON OF DUST CONCENTRATIONS (MPPCF) IN TALC PLANTS
4205 IN NEW YORK STATE

4207 A. Plants in St. Lawrence County

	Old (up to 1945)				New (1946-1958)			
	Low	Med	High	Av	Low	Med	High	Av
Mines								
Drilling	83	413	2,800	818	0	2	8	3
Mucking	2	30	475	120	2.5	4	5	4
Mills								
Crushing	22	69	690	180	3	13	360	32
Screening	43	61	136	69	8	35	68	37
Milling	32	75	271	92	5	15	40	20
Garners and separators	58	70	728	278	3	10	21	11
Bagging	26	129	520	151	5	17	90	24
Slow room	115	1,196	2,480	1,227	–	Discontinued		
Open chutes	21	83	440	125	–	"	"	–

WCD 001373

TABLE IV-1 (CONTINUED)

COMPARISON OF DUST CONCENTRATIONS (MPPCF) IN TALC PLANTS IN NEW YORK STATE

B. Plants in Lewis County

	Old (1940-1948)				New (1958)			
	Low	Med	High	Av	Low	Med	High	Av
Mines								
Drilling	(No dust counts done)				0	-	2.5	1
Mucking					2.5	5	7.5	5
Mills								
Crushing	104	128	280	171	19	23	41	27
Screening	152	352	672	386	69	106	113	96
Milling	47	242	575	266	13	15	58	29
Separators	179	565	1,090	537	25	26	60	37
Bagging	80	197	320	199	19	66	113	66

Adapted from reference [71]

The engineering control techniques instituted in 1945-1948 reduced markedly the concentration of airborne talc in the work environment and maintained this improvement through 1974, as indicated in the data in Table IV-2, compiled by Kleinfeld et al [74] in 1974. This trend was expected since there had not been any major change in the technology of underground talc mining after the introduction of wet drilling. It should also be pointed out that the frequency of the sampling, accuracy of the data, and representativeness of the samples are unknown.

WCD 001374

TABLE IV-2

COMPARATIVE TALC DUST CONCENTRATION (MPPCF) AT VARIOUS MINING AND MILLING OPERATIONS

	Pre-1945 through 1969						1972	
	Pre-1945		1946-1965		1966-1972			
	Av	Med	Av	Med	Av	Med	Av	Med
Drilling	818	413	5	3	19	19	7	7
Mucking	120	30	5	5	9	9	3	3
	Pre-1948		1948-1964					
Crushing	180	69	42	13	28	20	35	15
Screening	69	61	37	37	-	-	-	-
Milling	92	75	25	20	40	24	7	7
Garnering and separating	278	70	27	27	-	-	13	9
Pulverizing	-	-	28	28	-	-	-	-
Bagging	151	129	27	23	29	25	27	27
RR and truck loading	-	-	73	63	43	20	36	28
Blow room	1,227	1,196	-	-	-	-	-	-
Open chutes	125	83	-	-	-	-	-	-

Adapted from reference (74)

More recently, respirable dust measurements have been used to determine worker exposure to talc. Boundy et al (20) used this procedure to evaluate the work environment in three talc producing plants in Vermont in 1975 and

WCD 001375

1976. The miners were exposed at 0.6-2.0 mg/cu m, with the drillers, scraper,
and muckers exposed at the upper part of the range. The authors found that
laborers and maintenance personnel could also be exposed at high
concentrations, depending on their work assignments. In the open-pit and
walk-in mines, the average concentrations at all operations were higher than
in underground mines, with the highest exposure due to machinery used in open-
pit mines: the automatic-mining-machine operators were exposed at 5.8 mg/cu m
and drillers at 3.6 mg/cu m. Average concentrations in the milling plants
were 0.9-2.9 mg/cu m. The crushers, dry mill operators, baggers, and
palletizers were generally exposed at the higher concentrations.

Kennedy et al [20] also analyzed samples for asbestos and quartz content in
a Vermont talc producing facility. Using electron microscopy and step-
scanning X-ray diffraction analysis, the investigators found no asbestos
fibers in the samples. Fifteen percent of the bulk samples analyzed contained
small amounts (<5%) of quartz.

NIOSH conducted an industrial hygiene survey of a mine and mill in New
York State in 1975 [19] in which respirable dust concentrations and total dust
counts were two of the parameters measured. The TWA concentrations of
respirable dust ranged from 0.42 mg/cu m for maintenance mechanics to 1.29
mg/cu m for the scraper men. The corresponding dust count concentrations were
1.5 and 11.8 mppcf, respectively. The highest dust count concentration found
was 15.8 mppcf for the muckers; the respirable dust concentration was not
determined. In the mill, the TWA concentration respirable dust ranged from
0.25 to 2.96 mg/cu m. The millwright and his helper were exposed at
concentrations higher than 2 mg/cu m while the baggers were exposed at <0.5

WCD 001376

mg/cu m. Only a few dust counts were determined in the mill; they ranged from
4377 0.9 to 3.6 mppcf.

4379 As mentioned earlier, talc is almost always found in association with
4379 other minerals. Since associated asbestos fibers and free silica are major
4381 health concerns, their concentrations in workplace air have also been
4382 investigated. The NIOSH study [19] on a New York State talc operation
4383 mentioned above also determined asbestos fiber and free silica concentrations.
4385 The TWA fiber concentrations, determined by optical microscopy, ranged from
4386 1.7 to 9.8 fibers >5 (u)m/cc. The crusher operator, trammer, and sequman in
4387 the mine, and the foreman, laborer, crusher operator, secondary grinder,
4388 primary grinder, and bagger in the mill were exposed at more than 5 fibers >5
4389 (u)m/cc. Using electron microscopy, the TWA concentrations of all lengths of
4390 asbestos fibers ranged from 9.5 to 70.6 fibers/cc. The investigators also
4391 compiled previous data on fiber concentrations for this plant, as shown in
4393 Table IV-3. In the same study, analysis by electron microscopy revealed that
4394 38-45% of the airborne fibers were anthophyllite, 13-19% were tremolite, and
4395 the rest were not identified. The free silica concentrations found in the
4396 same plant were very low, with the highest TWA concentration found to be 0.04
4397 mg/cu m. This is lower than the TWA concentration of 0.05 mg/cu m of free
4398 silica recommended as the occupational exposure limit by NIOSH [130].

WCD 001377

TABLE IV-3

SUMMARY OF HISTORIC FIBER EXPOSURE MEASUREMENTS AT A MINING AND MILLING PLANT IN NEW YORK STATE

Job or Operation	Mean Fiber Concentration (fiber >5 fu/cc)						
						NIOSH	
	1970	1972	1973	1974	1975	1975	1976
Mine							
Drilling	8	4	1	1	1	3	24
Dragline loading	16	6	1	2	-	6	-
Tramming and loading	32	6	1	-	3	6	8
Primary crushing	260	22	5	9	20	10	25
Hoist loading	29	5	10	13	3	10	12
Mill							
Secondary crushing	13	5	14	6	9	5	18
Primary grinding	30	-	14	13	17	6	14
Secondary grinding	33	-	-	13	10	8	14
Bagging	30	-	11	15	6	5	14
Palletizing	27	-	8	15	-	4	-
Bulk loading	8	-	-	-	-	2	-
Loading bags	-	-	-	-	-	3	-
Other							
Millwright	-	-	9	-	-	2	-
Maintenance	-	-	14	-	-	2-4	38

Adapted from reference [19] and [131] (1970 data)

NIOSH [132], in 1972, conducted a talc dust industrial hygiene survey at a rubber band production plant. At this plant, talc was being used in a careless manner and in an amount in excess of that needed for lubrication. In addition, ventilation and housekeeping within the workplace were poor. As a result, high dust concentrations were found. The respirable dust TWA concentrations for 8 hours were 2.5-7.6 mg/cu m (average 4.8 mg/cu m) for the extruders, 5.2 and 6.1 mg/cu m for two vulcanizers, and 0.9 and 1.3 mg/cu m

WCD 001378

for two cutters. The average total dust concentration ranged from 5.4 mg/cu m for the cutter in the sizing building to 141.4 mg/cu m for the vulcanizers. In addition, fiber concentrations, as determined by phase contrast optical microscopy, ranged from 4.9 to 19.2 fibers >5 um/cc, except for the packer who was exposed to only 1 fiber/cc. The dust contained 2-3% free silica. Subsequently, the plant substituted antistick plastic sheets for some of the talc and generally minimized the use of talc, improved the existing ventilation, added new ventilation systems, and used a vacuum cleaner for floor cleaning. A reevaluation [133] in 1973, showed that these modifications had been effective in improving the work environment. The respirable dust concentrations for the extruder were 4.2 mg/cu m with the improved ventilation and 2.2 mg/cu m when the additional ventilation was also used, 1.9 mg/cu m for the packer (in the same room as the vulcanizers), and 3.0 mg/cu m for a laborer operating the vacuum cleaner.

Additional environmental data [22] were obtained from some of the plants visited in conjunction with the development of this document. In mining and milling plants surveyed between September 1977 and February 1978, the miners were exposed to respirable dust at an average concentration of 41 mg/cu m except for the drillers and mining-machine operators in a walk-in mine, whose exposure was found to be >2 mg/cu m. In the milling plants, the workers were generally exposed at 1-3 mg/cu m, with the baggers, laborers, and dry mill operators exposed at the upper part of the range, although in a newly designed and constructed milling facility, the average exposure was only <0.5 mg/cu m. In a plant that uses talc as a major ingredient, the respirable dust concentrations were generally below 1 mg/cu m throughout the plant when

WCD 001379

surveyed in 1976-1977. Some areas in the plant were found to have
4488 concentrations up to 4 mg/cu m.

4491 Engineering Controls

4494 During the early 1950's, a substantial reduction in dust concentrations in
4495 mining and milling operations was reported, as a result of great improvements
4496 in engineering techniques used in these processes.

4498 In the past, high dust concentrations occurred in mines during dry
4498 drilling, blasting, and mucking operations (38,129). However, after wet
4499 drilling techniques were instituted, airborne dust concentrations were
4501 markedly reduced (39). Similarly, a marked reduction in dust levels was
4502 reported in the mills after installation of engineering controls such as
4503 enclosure of elevators and chutes, automatic bagging machines, automatic
4504 railroad car loading, pneumatic conveyance, local exhaust ventilation, and by
4506 discontinuing the use of blowroom.

4508 Local exhaust ventilation can also be effectively used to control dust
4509 levels in operations such as the manufacture of ceramics, paint, paper,
4510 roofing, and other materials that extensively use talc or talc-containing
4511 materials. Information on ventilation design and control procedures can be
4512 found in Industrial Ventilation....A Manual of Recommended
4513 Practice (134), and in ANSI's Fundamentals Governing the Design
4514 and Operation of Local Exhaust Systems Z9.2-1971 (135).

WCD 001380

WCD 001381

Commercially, the term "talc" refers to a powder consisting of a mixture of pure talc and other minerals. The associated minerals give talc the physical properties required for its diverse industrial applications. Since talc produces adverse health effects and sometimes occurs mixed with asbestos minerals known to produce cancer in humans, the employer should supplement engineering and administrative controls in all workplaces where talc is produced, handled, used, or stored with appropriate work practices to further reduce worker exposure. Work practices programs should be oriented toward proper methods for handling talc, selection, use, and care of appropriate personal protective clothing (dust-resistant garments) and equipment, and procedures for cleaning up spills and responding to emergencies. In addition, a regular program of instruction must be established to ensure that all potentially exposed employees are familiar with the specific hazards of talc and appropriate precautionary handling procedures.

Occupational exposure to talc may occur in three types of occupational sites: mines, mills, and end-user facilities. The nature of exposure varies according to where the exposure occurs. In mines, dust particles are generally coarser than in mills or end-user facilities in which there is exposure to talc. In mills, particles may range from very coarse to respirable size depending on the emission point in the process. At the end-user facilities, fine particles are usually expected. In addition to these apparent differences in exposure, work procedures are also different

therefore, in protecting workers from exposure to talc at concentrations exceeding the recommended environmental limit, different work practices may be required to cope with the different situations encountered.

In mining and milling operations, the employer must adhere to the safety and mining procedures and regulations required by the Mine Safety and Health Administration (MSHA). Briefly, mining personnel engaged in such processes as wet drilling, blasting, machine mucking, and stopping should be required to wear proper protective clothing and equipment, since process enclosure is impossible. In operations using an automatic-mining-machine, an atmosphere-controlled cabin should be provided for the operators.

Processes in the milling plants generally include crushing, grinding, drying, classifying, bagging, and palletizing. A typical process flow diagram is shown below:

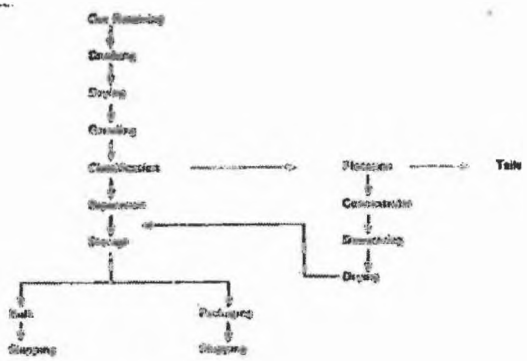


Figure V-1 TYPICAL MILLING FLOW DIAGRAM

WCD 001382

Most of the process equipment involved in milling plants is enclosed and operated under negative pressure [22]. Thus, talc dust may be dispersed into the workplace primarily at transfer points and from openings or cracks resulting from failure of the process equipment. Therefore, it is important to maintain all process equipment in proper working order and to check routinely for wear and tear. If defects are found, properly protected personnel should promptly repair the equipment. Any spill resulting from equipment failure or rupture of bags should be promptly removed to prevent dispersal into the workroom air.

At the end-user facilities talc has various industrial applications because of its diverse physical properties [6]. For example, cosmetic grade talc (>90% pure) is used to make baby powder and as a tablet filler in pharmaceutical products. Industrial grade talc is used in paint, ceramics, paper, and rubber as filler, inert ingredient, or surfacing agent. Depending on the amount and manner in which talc is used in a particular process, the exposure concentrations may vary by several orders of magnitude [22]. Engineering controls, such as process enclosure and exhaust ventilation, should be used to control talc concentrations in workroom air. Protective clothing and respirators should be used in cleanup operations, maintenance, repair, or emergency situations.

As a fundamental objective, the employer should maintain a clean workplace to minimize dust exposure in order to protect employee safety and health. To prevent dust accumulation in the workplace, workers should frequently clean the floors and the exteriors of process equipment with a vacuum cleaning system. Local exhaust systems equipped with flexible ducts

WCD 001383

may be used to remove settled dust from the equipment. Although brooms and shovels have often been used for cleaning floors, vacuum systems are considered more effective in reducing workers' exposure to talc because they disperse very little dust into the air in comparison to brooms and shovels. All personnel engaged in cleaning activities should be properly protected from dust exposure.

Under normal operating conditions, respirators should not be used as a substitute for proper engineering controls. Respirators should be used only during emergencies, during maintenance activities, during cleaning of equipment, and when appropriate engineering controls or administrative measures are being installed or tested. Respirators conforming to Table I-1 and approved under 30 CFR 11 should be provided to employees, and a respiratory protective program should be established in compliance with the current Federal standard, 29 CFR 1910.134 or 30 CFR 55, 56, 57.5-5, whichever is applicable. Emphasis should be directed toward providing clean, well-maintained, and fitted respirators for use in emergencies and unusual circumstances. The interior of the facepiece should not be contaminated with talc.

To prevent excessive dust deposits on work clothes, especially during nonroutine operations, employees should wear dust-resistant garments, with securable flaps over pockets and with no folds, cuffs, or tears in their work clothes. The employer should encourage employees to cover unbandaged open wounds, unless medically contradicted, to avoid talc contamination. A vacuum system should be used to remove dust from the work clothes. Work and street clothes should be kept in separate lockers. Shower and locker

WCD 001384

room facilities should be provided and the employees should be encouraged
4635 to shower before leaving the work area at the end of a shift. Because of
4636 possible synergistic effects of cigarette smoking and talc in causing
4637 pulmonary diseases [17], smoking should be discouraged.

4640 Before workers enter a confined space, the process involved should be
4641 shut off and a worker should check the space for oxygen deficiency and the
4643 concentration of talc dust and any other air contaminants known to be
4644 present. If the confined space is deficient in oxygen or the recommended
4645 environmental limit for respirable talc dust is exceeded, appropriate
4646 respirators should be required. A second worker should be available to
4648 assist in the event of an emergency.

4650 Employers should require new employees to participate in an orientation
4651 program in which they are informed of the adverse health effects that could
4652 result from long term exposure to talc at concentrations exceeding the
4654 recommended environmental limit. During this initial orientation, and
4655 where the particular situation warrants, employer should make certain that
4656 employees understand that in some operations talc may be mixed with other
4658 minerals, such as tremolite and anthophyllite, the fibrous forms of which
4659 are considered to be carcinogenic to humans. Written information on the
4660 adverse health effects and signs and symptoms that can be caused by
4661 exposure to talc and associated minerals should be provided to employees.
4662 New information should be posted in areas accessible to employees.

4665 An ongoing education program should be established to allow an
4667 opportunity for employees to meet with management to review safety
4668 procedures and new toxicologic findings. Both the orientation and

WCD 001385

continuing education programs should be conducted by personnel qualified by
4670 experience or training in occupational safety and health.

WCD 001386

4680 Basis for Previous Standards

4683 In 1946, the American Conference of Governmental Industrial Hygienists
4684 (ACGIH) [136] established a maximum allowable concentration (MAC) for talc
4685 of 20 mppcf of air as determined by standard light field counts [137]. The
4687 basis for this recommendation was not given. MAC's were redefined as
4688 threshold limit values (TLV's) in 1948 by the ACGIH and a TLV concentration
4689 of 20 mppcf was adopted for talc at that time. The TLV for talc remained
4690 unchanged until 1962 when a stipulation was added that the TLV applied only
4692 to airborne talc dust containing <1% crystalline silica [138]. The new
4693 silica TLV was to apply to any mineral dust with a content >1% silica.

4696 The Documentation of the Threshold Limit Values [139],
4697 published in 1963, indicated that the basis for the talc TLV was a number
4698 of clinical studies that associated exposures to talc with pneumoconiosis
4700 [136,37,140,129,141,142,143,144, 45,145,39,146,147,148]. In most of these
4702 studies, workers were exposed to talc containing tremolite or other
4704 contaminating minerals. Hogue and Mallette [149] reported that workers
4705 exposed to talc dust at average concentrations of 15-50 mppcf for 10-35
4707 years showed no evidence of pneumoconiosis. Schepers and Durkan [78]
4709 analyzed the complex interplay between talc, tremolite, and quartz from
4710 human studies, and from many reported cases of talc pneumoconiosis that
4711 resembled asbestosis. The ACGIH [139] considered that the TLV applied to
4712 commercial talc, which includes a variety of products with similar physical
4714 characteristics regardless of actual talc content, rather than to pure

WCD 001387

talc. The recommended TLV was based largely on the report of Dreessen and
4716 Dallavalle [37] on 60 workers who handled Georgia talc containing 10%
4718 tremolite. The authors found no pneumoconiosis in workers who were exposed
4719 to talc at average dust concentrations of 17 mppcf, but found severe and
4720 disabling cases of workers exposed to talc at average dust concentrations
4722 of 135 and 300 mppcf. The documentation also cited studies by Kleinfeld et
4723 al [39] and Nesnite et al [71] on workers exposed to talc that contained
4724 tremolite as support for the 20-mppcf TLV for exposure to talc dust.

4726 The ACGIH in Threshold Limit Values for 1964 [150] added a
4729 TLV for mixtures of mineral dusts to Appendix B. The general formula for
4730 mixtures was used to indicate that, when two or more biologically active
4731 mineral dusts are present, their combined effect, as calculated by the
4733 expression in the TLV manual, rather than that of either individually,
4734 should be given primary consideration in the TLV [150].

4737 In 1967, the ACGIH [151] added tremolite as a hazardous mineral dust,
4738 and established a TLV of 5 mppcf based on the TLV for asbestos, since
4739 fibrous tremolite is a form of asbestos [152]. In 1968 [153] and 1969
4740 [154] the ACGIH published notices of intended change to lower the asbestos
4741 TLV to 12 fibers/cc for fibers >5 µm in length or 2 mppcf. In 1970, the
4742 TLV of 5 mppcf for asbestos was extended to talc containing asbestos fibers
4743 and to tremolite asbestos. The intended change in this TLV was revised in
4745 1970 [155] to 5 fibers/cc for fibers >5 µm in length. The TLV also
4746 proposed 15-minute ceiling limit of 10 fibers/cc for fibers >5 µm in
4747 length that could be exceeded no more than five times daily. This intended
4749 change in the TLV for asbestos including fibrous talc and tremolite, was

WCD 001388

formally adopted as a TLV in 1974 [156].

According to the 1971 Documentation of Threshold Limit Values for Substances in Workroom Air [157], the ACGIH TLV for nonfibrous talc of 20 mppcf was based largely on the work of Dreessen and Dallavalle [37]. The 1971 documentation stated that the fibrous variety of talc and its associated amphiboles, such as tremolite and anthophyllite, contain fibers that are classified as asbestos. Porro et al [140] investigated 15 cases of talcosis, including 5 for which autopsies were performed, and reported that asbestos bodies were almost always present in the fibrotic areas. They also noted a degree of similarity between asbestosis and pneumoconiosis induced by talc. Siegel et al [36] reported on 221 talc miners and millers exposed to talc containing tremolite and found an advanced fibrosis incidence rate of 14.5%. McLaughlin et al [136] indicated that talc pneumoconiosis could be caused only by the fibrous variety of talc, and that asbestos was more actively fibrogenic, possibly because of its higher number of fibers. In autopsies of eight talc workers, Schepers and Durkan [139] found microscopic indications suggesting that tremolite was the main pathogenic agent in the talc lung lesions. Kleinfeld et al [41] reported autopsy findings on six talc workers in which the "asbestos-like bodies" found in the respiratory bronchioles or in fibrous tissues were indistinguishable from those found in asbestosis. Thus, the ACGIH [157], because of the similarity of the fibrotic reactions produced by talc and asbestos, recommended a TLV of 5 fibers/cc for fibers >5 (um in length for talc containing tremolite. The adopted TLV's [159] in 1977 included values for nonfibrous talc (20 mppcf), and tremolite as well

WCD 001389

as a value for asbestos. The asbestos TLV was 5 fibers/cc for fibers >5
4787 tu/m in length.

4789 The present US Federal Standard (29 CFR 1910.1000, and 1910.1001 30 CFR
4790 55, 56, 57.5-1) for workplace exposure to talc is an 8-hour TWA
4791 concentration limit of 20 mppcf for nonfibrous talc containing <1% quartz.
4793 For comparison, a list of environmental limits for exposure to talc in
4794 foreign countries is shown in Table VI-1. For talc with asbestos minerals
4795 in the United States, the asbestos standard is used, which is an 8-hour TWA
4797 concentration limit of 2 fibers/cc for fibers >5 tu/m in length. In
4798 addition, the concentration of talc with asbestos minerals is not to exceed
4800 10 fibers/cc for fibers longer than 5 tu/m for any period of time (i.e. a
4801 ceiling limit). The standard for talc is based on the TLV for workplace
4803 exposure adopted by the ACGIH in 1968 for OSHA and in 1973 for MSHA. The
4805 talc with asbestos minerals standard is based largely on work done by the
4806 British Occupational Hygiene Society for a proposed standard for asbestos.

WCD 001390

TABLE VI-1

OCCUPATIONAL ENVIRONMENTAL LIMITS FOR TALC
IN FOREIGN COUNTRIES

Country	Standard
Australia	2.5 mg/cu m
Czechoslovakia	6 mg/cu m
Finland	700 ppcc*
Hungary	200 ppcc* (5.7 mppcf)
Italy	750 ppcc* (21.3 mppcf)
USSR	4 mg/cu m
Yugoslavia	700 ppcc (19.8 mppcf)

*parts per cubic centimeter

Adapted from reference [160]

Basis for the Recommended Environmental Standard

(a) Permissible Exposure Limit

Most studies of health effects of talc on workers found in the available literature do not adequately characterize talc by source, mineral composition or particle size. Evaluation of many human and animal studies is complicated because talc is often found mixed with free silica and asbestos minerals, such as chrysotile and the microscopic fibrous forms of tremolite, anthophyllite,

WCD 001391

and actinolite. Environmental data have usually been reported as the number of particles of total dust determined by counting methods, although some recent studies report airborne dust in the workers' breathing zone as respirable dust measurements.

Since silica contamination of talc is possible, NIOSH recommends that the silica content be determined by X-ray diffraction or equivalent methods as stated in the NIOSH Manual of Analytical Methods [114]. Talc containing crystalline free silica should comply with the environmental limit for silica proposed by NIOSH in its criteria document on crystalline silica [161].

Also, since talc is often contaminated with asbestos minerals, NIOSH also recommends compliance with the environmental limit for asbestos fibers, when present, in accordance with the NIOSH revised recommended standard on asbestos [101].

A review of the literature has revealed little information suggesting carcinogenic, mutagenic, teratogenic, or reproductive effects of talc without asbestos or free silica on humans or animals. A number of reports have revealed that exposure of workers to talc without asbestos and with less than 1% free silica produced adverse respiratory effects and changes in X-ray films [164,32, 33,35,17,58,95]. Workers exposed for 10 years or longer at average concentrations greater than 20 mppcf developed X-ray film evidence of pneumoconiosis [32,33]. Rubino et al [65] concluded that talc millers exposed to talc for an average of 22 years at an average concentration estimated by the authors as 11 mppcf showed X-ray film findings consistent with pneumoconiosis. They suggested a level of 4 mppcf might be necessary to prevent the initial X-ray film changes of pneumoconiosis from developing

WCD 001392

during a working lifetime of 40 years.

For speculative purposes, a factor for converting mppcf to mg/cu m can be derived for the Rubino study if the shape, size, and distribution of sizes of particles in bulk Italian talc is pertinent for airborne talc, if the average density of talc is 2.7 g/cc, and if the average particle diameter and average thickness of the particles are 4 (u) and 0.2 (u), respectively. Analysis of bulk Italian cosmetic grade talc shows that it consists of platelets with an average ratio of diameter to thickness of about 20:1, and a distribution of particle sizes tightly clustered around the average (Don Ferry, personal communication, January 1979). The range of densities for talc is 2.58-2.83 g/cc (median 2.70) [1].

Under these conditions 1 mppcf can be calculated to equal 0.24 mg/cu m; thus, Rubino's suggested maximum concentration of particles that will not induce initial signs of pneumoconiosis would translate to approximately 1 mg/cu m.

Fine et al [17] found significantly increased incidences of cough, excess phlegm, and wheezing in workers exposed for an average of 8.9 years to talc containing <1% free silica and no asbestos fibers. Past talc concentrations were unknown, but job exposure concentrations at the time of the study ranged from 0.47-3.55 mg/cu m. Significant decreases in FEV 1 were found by multiple regression analysis among workers exposed to talc for more than 10 years. When this cohort was subdivided in accordance with smoking history, significant excesses were found only in those talc workers who were former or current smokers. Workers in this study with <10 years exposure to talc did not have significant decreases in FEV 1.

WCD 001393

Wagman et al [68] concluded from a multiple regression analysis of pulmonary function measurements in a group of Vermont talc workers, that exposure concentrations near the range of 1-2 mg/cu m appeared to be safe. They reached this conclusion because a significant effect of talc exposure on pulmonary function measurements could not be demonstrated in nonsmoking workers exposed in this range. Although a significant effect of talc exposure on FEV 1 in smokers was demonstrated in this study, it was noted that smokers were exposed at an average concentration of 1.91 mg/cu m as opposed to that of 1.57 mg/cu m for nonsmokers. The authors also stated that major changes in engineering controls had taken place while these workers had been employed and that past exposures had probably been much higher than those measured in the study.

Although the evidence presented in any one of these papers [17,65,68] is not conclusive for the purposes of setting a permissible exposure limit, together they indicate that exposure at levels >1 mg/cu m of talc not containing asbestos or significant levels of free silica over a normal working lifetime may cause adverse pulmonary effects in talc workers who smoke [17,65]. Based largely on the data of Wagman et al [68], a concentration of 1.5 mg/cu m of respirable talc dust appears to be safe for non-smoking workers. However, there is insufficient evidence at this time to justify a conclusion that this concentration will be safe for workers who smoke. For this reason, NIOSH recommends that the concentration of talc dust not containing >0.1 asbestos fibers/cc or >5% (1mg/cu m free silica in the breathing zone of workers, be controlled so that the concentration at which the workers are exposed is no greater than a TWA concentration of 1.5 mg/cu m

WCD 001394

WCD 001395

of mass respirable dust as determined by a gravimetric method.

(b) Sampling and Analysis

The recommended method of sampling and analysis should be simple, sensitive, and specific for the mineral analyzed. In addition, sampling should be representative of the worker's breathing zone air without impeding normal job performance. Because of the complex mineral composition of talc, proper characterization of workers' exposure requires several steps of sampling and analysis. First, to evaluate dust exposure in a workplace where talc is processed, handled, used, or stored, respirable dust sampling is recommended. Secondly, exposure to two important impurities commonly found in talc, free silica and asbestos fibers, should also be determined.

The details of respirable dust sampling and analysis are given in Appendix I. The concentration of crystalline silica can be determined from the collected respirable dust samples using the X-ray diffraction method as recommended in the NIOSH Manual of Analytical Methods (114). For determination of airborne asbestos fiber concentrations, the open-face filter sampling and phase-contrast counting method as recommended in the NIOSH revised asbestos standard can be used. However, because the mineralogic nature of the fibers counted is uncertain with this method, an advanced procedure, selected area electron diffraction, will be required to positively identify fibers as amphibole or another form of asbestos. To make these procedures feasible as a routine method, NIOSH recommends a scheme whereby the selected area electron diffraction method need be used only in a limited number of cases. As a first step, bulk samples of talc should be examined periodically for their asbestos content using the transmission electron

microscopy with selected area electron diffraction technique. If asbestos fibers are found, phase-contrast counting of fibers collected from workroom air should be done. If the fiber count exceeds the recommended standard of 0.1 fibers/cc, the transmission electron microscopy with selected area electron diffraction method should be used to determine the concentration of true asbestos fibers in workroom air. Details of this method are given in Appendix II.

Respirable dust sampling is simple and straightforward and provides information closely related to hazards of talc particle inhalation. Analysis of free silica content by X-ray diffraction is a specific analysis for various forms of free silica and has a detection limit of 5 ug; however, the lower limit of quantification is 20 ug/sample. The presence of specific elements such as iron may result in high background intensity.

(c) Medical Surveillance and Recordkeeping

Human and animal studies have demonstrated that exposure to talc produced respiratory effects and pneumoconiosis. It has also be demonstrated in humans that smoking increases the risk of respiratory effects [17,68]. A medical surveillance program, including preplacement and periodic medical examinations, should be instituted for screening and monitoring workers potentially or already at hazard of exposure to talc. This surveillance program should establish a data base that includes information on smoking, medical and occupational histories, chest X-ray film, and pulmonary function tests including FVC and FEV 1.

Medical records should be maintained for at least 30 years beyond the duration of employment to help safeguard the health of current and future

WCD 001396

employees.

(d) Personal Protective Equipment and Clothing

Because granulomas may develop from contact with talc on open skin wounds, protective clothing may be necessary. To minimize the possibility of excessive dust exposure, employees should use respirators when engineering controls cannot maintain the airborne talc concentrations of the workplace below the recommended environmental limit.

(e) Informing Employees of Hazards

Employees who may be occupationally exposed to talc should be advised of the adverse health effects from such exposure. The probable synergistic effects between cigarette smoking and exposure to talc also should be emphasized. Other information such as the source of exposure, information about the methods of preventing or controlling exposure to talc dust of various composition, and the importance and advantages of environmental and medical surveillance programs should be made available to the employees. All information should be given to employees prior to assignments where there will be exposure to talc, and the information should be reviewed periodically thereafter.

(f) Work Practices

Engineering controls, such as process enclosure and local exhaust ventilation, should be used to control the concentrations of dust in workroom air. The process and control equipment should be routinely checked and maintained to ensure effectiveness. Good work practices, such as frequent housekeeping by vacuuming, prompt cleanup of spills, effective respiratory protection programs, proper waste disposal, good personal hygiene, and

WCD 001397

adequate training, should be instituted to minimize employees' exposure to
5067 talc dust.

5070 (g) Monitoring and Recordkeeping Requirements

5073 To characterize the concentration of respirable airborne talc dust in the
5074 employees' breathing zones, the employer should conduct periodic industrial
5075 hygiene surveys. Surveys should be conducted at least annually and within 30
5076 days of any process change likely to result in an increase in the
5077 concentrations of respirable airborne talc. If monitoring reveals that an
5078 employee is exposed above the recommended environmental limit, the employee
5079 should be promptly notified, improved engineering controls should be
5080 initiated, and the employee's exposure should be monitored weekly until two
5082 successive determinations, at least 1 week apart, indicate that the
5083 environmental concentration is at or below the recommended environmental
5084 limit. Records of workplace environmental monitoring should be kept for at
5085 least 30 years after the employee's last exposure to talc.

WCD 001398

WCD 001399

VII. RESEARCH NEEDS

Epidemiology Research

More comprehensive epidemiologic studies concerning exposure to talc without asbestos minerals are needed along with follow-up studies of populations and cohorts already reported on. The effects of low level exposures, as measured by personal samplers, should be examined in these prospective studies. Studies of this nature should identify smokers as a subgroup, since a preliminary study by Fine et al [17] indicated that smokers may be affected to a greater extent than nonsmokers. A study with a control group that has been matched for factors that are known to influence pulmonary function measurements, such as height, smoking history, and age, would be especially useful in isolating the effects of occupational exposure of a population to talc. Such a study might further develop the multiple regression model and increase the accuracy of the regression coefficients as developed by Fine et al [17] by basing the statistical analysis on a larger population of exposed workers.

Excesses of lung cancer have been reported in human mortality studies of populations exposed to talc mixtures [63,68,74]. Exposure of these populations to many possible carcinogens, including asbestos, confound the findings and suggest that further research in this important area is needed. Such studies might compare cancer rates in populations occupationally exposed to relatively pure talc with a carefully matched control population. Further studies relating environmental sampling to actual human exposure in the workplace are also needed.

5127 Animal Research

5130 Although talc has been widely used in modern times in a variety of
5131 products that involve the exposure of a large number of people, basic research
5132 questions concerning talc have not been completely resolved. Among these is
5133 the pathogenicity of pure talc and the role of substances that commonly occur
5134 with talc. Lesions induced by the common contaminants of talc, asbestos
5136 [78,87] and free silica [74,79], have been studied, but those due to other
5138 minerals that may occur along with talc, such as dolomite, chlorite, and
5139 magnesite, have not. Animal inhalation studies that evaluate the degrees of
5141 pathogenic effects on pulmonary tissue of pure talc, dolomite, chlorite,
5142 magnesite, non-fibrous tremolite, and the talc-related mineral pyrophyllite,
5144 alone and in combination, are needed.

5146 Animal studies also often yield useful information concerning dose-
5146 response relationships of a compound. Bethge-Iwanska [77] and Wehner et al
5148 [78] both performed animal inhalation studies that may be comparable with
5149 human occupational exposure. Experimental problems with both studies, such as
5150 the widespread incidence of interstitial pneumonia in the Wehner study and the
5151 lack of characterization of the talc in the Bethge-Iwanska study, suggest that
5152 further animal studies at similar concentrations are needed. These studies
5154 should address the entry and removal of talc from the lungs with particular
5155 regard to the role of the alveolar macrophages, species or sex differences in
5156 the clearance response mechanism, and further development of dose-response
5157 relationships.

5159 Several studies have examined the carcinogenic potential of talc in a
5160 variety of species [67,75,86]. The mutagenic, teratogenic and reproductive

WCD 001400

effects have not been thoroughly investigated and the mutagenic studies that
5162 have been done [88] are not definitive. Thus, further studies in these areas
5163 are also needed.

5166 Sampling and Analytic Studies

5169 Precise, simple, and inexpensive methods to simultaneously identify and
5170 quantify morphology, crystal structure, and mineral composition of a talc
5171 mixture should be developed.

WCD 001401

VIII. REFERENCES

1. Mulryan HF: Talc, in Kirk-Othmer Encyclopedia of Chemical Technology, ed 2 rev. New York, Interscience Publishers, 1969, vol 19, pp 608-14

2. Campbell WJ, Blake RL, Brown LL, Cather EE, Sjoberg JJ: Selected Silicate Minerals and Their Asbestiform Varieties, Mineralogical Definitions and Identification-Characterization. Information Circular No. 8751. College Park, MD, US Dept of the Interior, Bureau of Mines, 1977, 61 pp

3. Langer AM: Aspects of mineralogy of talc, in Goodwin A (ed.): Proceedings of the Symposium on Talc, Washington, D.C., May 8, 1973, Information Circular No. IC 8639. US Dept of the Interior, Bureau of Mines, 1974, pp 82-88

4. Rohl AN, Langer AM, Selikoff IJ, Tordini A, Klimentidis S, Bowes DR, Skinner DL: Consumer talcums and powders--Mineral and chemical characterization. J Toxicol Environ Health 2:255-84, 1976

5. McCrone LB: Analysis of Talc by Xray Diffraction and Polarized Light Microscopy. Cincinnati, US Dept of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, 1977, 52 pp

6. Ros LA: Talc and pyrophyllite, in Industrial Minerals and Rocks. Salt Lake City, UT, Society of Mining Engineers of AIME, 1968, pp 1127-47

7. Weiss S, Bestiner EA: Commercial talc and talcosis. Arch Environ Health 14:304-08, 1967

WCD 001402

5239 8. Natch IF, Gross P: Pulmonary Deposition and Retention of Inhaled
5240 Aerosols. New York, Academic Press, 1964, pp 147-84

5249 9. Criteria for a Recommended Standard--Occupational Exposure to Asbestos,
5250 Publication No. HSM 72-10267. Cincinnati, US Dept of Health, Education, and
5251 Welfare, Public Health Service, Health Services and Mental Health
5252 Administration, National Institute for Occupational Safety and Health, 1972,
5254 second printing, 130 pp

5257 10. Revised Recommended Asbestos Standard, DHEW (NIOSH) Publication No. 77-
5257 169. Cincinnati, US Dept of Health, Education, and Welfare, Public Health
5259 Service, Center for Disease Control, National Institute for Occupational
5260 Safety and Health, 1976, 96 pp

5262 11. McCrone WC, McCrone LB: Light microscopy of microfibers--Uses and
5263 limitations. In Asher IE, McGrath PP (eds.): Symposium on Electron
5265 Microscopy of Microfibers--Proceedings of the First FDA Office of Science
5266 Summer Symposium. US Dept of Health, Education, and Welfare, Public Health
5267 Service, Food and Drug Administration, Office of Science, Bureau of
5268 Biologics, Bureau of Drugs, Bureau of Foods, 1976, pp 37-43

5271 12. Saundre AV, Norwood CF, Stockham JD: Electron Microscopy Measurement of
5272 Airborne Asbestos Concentrations--A Provisional Methodology Manual, EPA-
5274 600/2-77-178, rev. Research Triangle Park, NC, US Environmental Protection
5275 Agency, Office of Research and Development, Environmental Sciences Research
5276 Laboratory, 1978, 57 pp

5278 13. Crelley LJ, Kay MM, Groth DH, Leinhart MS, Lieb MW: Fibrous and mineral
5279 content of cosmetic talcum products. Am Ind Hyg Assoc J 29:350-54, 1968

5286 14. Thrush PW (ed.): A Dictionary of Mining, Mineral, and Related Terms.
5287 US Dept of the Interior, Bureau of Mines, 1968, pp 464,505,1036

5290 15. Haner DN, Rolls FR, Schelz JP: Characterization of talc and associated
5291 minerals. Am Ind Hyg Assoc J 37:296-304, 1976

WCD 001403

5299 16. Talc, Soapstone, and Pyrophyllite, Preprint from Bulletin No. 667. US
5300 Dept of the Interior, Bureau of Mines, 1975, 12 pp

5302 17. Fine LJ, Peters JM, Burgess WA, Di Berardinis LJ: Studies of
5303 respiratory morbidity in rubber workers--Part IV. Respiratory morbidity in
5304 talc workers. Arch Environ Health 31:195-200, 1976

5309 18. Dement JM, Gamble JF, Brown D, Wagoner JK: Health Aspects Related to
5311 Miners and Millers Occupationally Exposed to Asbestiform Talc. Cincinnati,
5312 US Dept of Health, Education, and Welfare, Public Health Service, Center for
5313 Disease Control, National Institute for Occupational Safety and Health,
5314 Division of Surveillance, Hazard Evaluations and Field Studies, 125 pp
5315 (unpublished)

5317 19. Dement JM, Zumwalde RD: Final Report--Industrial Hygiene Study on the
5318 Gouverneur Talc Company, Number One Mine and Mill--Balmat, New York--Volume
5319 I. Cincinnati, US Dept of Health, Education, and Welfare, Public Health
5321 Service, Center for Disease Control, National Institute for Occupational
5322 Safety and Health, Division of Surveillance, Hazard Evaluations and Field
5323 Studies, 1977, 79 pp

5325 20. Soundy MG, Gold K, Burgess WA, Dement JM: Exposure to industrial talc
5326 in Vermont talc mines and mills. Presented before the American Industrial
5327 Hygiene Association Conference, New Orleans, Louisiana, May 26, 1977, 21 pp

5334 21. Talc and Pyrophyllite in 1976, in Mineral Industry Surveys, US Dept of
5335 Interior, Bureau of Mines, Division of Nonmetallic Minerals, 1978, 9 pp

5338 22. Plant Observation Reports and Evaluation. Menlo Park, CA, SRI
5339 International, 1979 (submitted to NIOSH under Contract No. CDC 210-77-0015)

5347 23. Thorel C: [Soapstone silicosis--A contribution to the pathological
5348 anatomy of silicosis.] Beitr Pathol Anat Allg Pathol 28:85-101, 1696 (Ger)

WCD 001404

5355 24. Talc, in Occupation and Health--Encyclopedia of Hygiene, Pathology and
5356 Social Welfare. Geneva, International Labour Office, 1934, vol II, pp 1005-06

5364 25. Zanelli A: [Pneumoconiosis from talc used in a tire factory.] Med Lav
5366 22:3-16, 1931 (Ita)

5372 26. Haynes F: Experimental dust inhalation in guinea-pigs. J Hyg 31:90-
5374 123, 1931

5381 27. Policard A: [Action of talc dust on the lungs--Experimental study.]
5383 Arch Mal Prof Hyg Toxicol Ind 2:530-39, 1939-40 (Fre)

5389 28. Antopol W: Lycopodium granuloma--its clinical and pathologic
5390 significance together with a note on granuloma produced by talc. Arch Pathol
5392 18:326-31, 1933

5397 29. Fienberg R: Talcum powder granuloma. Arch Pathol 24:36-42, 1937

5406 30. Schulz HZ, Williams CH: Commercial talc--Animal and mineralogical
5407 studies. J Ind Hyg Toxicol 24:75-79, 1942

WCD 001405

5414 31. Millman N: Pneumonoconiosis due to talc in the cosmetic industry.
5416 Occup Med 4:391-94, 1947.

5423 32. Fristadt B, Mattsson SB, Schutz A: [Talcosis by exposure to granular
5424 talc in a rubber industry.] Nord Hyg Tidskr 49:66-71, 1968 (Swe)

5431 33. Scansetti G, Gaido PC, Rasetti L: [Pneumoconiosis in workers processing
5432 talcum.] Med Lav 54:680-82, 1963 (Ita)

5438 34. Rubino GF, Scansetti G, Piolatto G, Romano CA: Mortality study of talc
5439 miners and millers. J Occup Med 18:185-93, 1976

5446 35. Scansetti G, Rasetti L, Ghemi F: [Clinical and radiological evolution
5447 of pneumoconiosis in the talc extracting industry.] Med Lav 54:746-49, 1963
5449 (Ita)

5453 36. Dreessen WC: Effects of certain silicate dusts on the lungs. J Ind Hyg
5455 15:66-78, 1933

5462 37. Dreessen WC, DallaValle JM: The effects of exposure to dust in two
5463 Georgia talc mills and mines. Public Health Rep 50:131-43, 1935

WCD 001406

5470 38. Siegel W, Saith AN, Greenburg L: Report on study of talc miners and
5471 millers in St. Lawrence County, N.Y. Ind Bull NY State Dep Labor 22:430-
5472 37,468-69, 1943

5478 39. Kleinfeld M, Messite J, Taborshaw IR: Talc pneumoconiosis. AMA Arch
5480 Ind Health 12:68-72, 1955

5483 40. Kleinfeld M, Messite J, Shapiro J, Swencicki R: Effect of talc dust
5484 inhalation on lung function. Arch Environ Health 10:431-37, 1965

5492 41. Kleinfeld M, Ciel CP, Majeranowski JF, Messite J: Talc pneumoconiosis--
5493 A report of six patients with postmortem findings. Arch Environ Health 7:107-
5494 21, 1963

5501 42. Kleinfeld M, Messite J, Kooyman C, Shapiro J: Pulmonary ventilatory
5502 function in talcosis of lung. Dis Chest 46:592-98, 1964

5509 43. Kleinfeld M, Messite J, Shapiro J, Swencicki R, Sorfaty J: Lung
5510 function changes in talc pneumoconiosis. J Occup Med 7:12-17, 1965

5516 44. Miller A, Teirstein AS, Bader ME, Bader RA, Selikoff IJ: Talc
5519 pneumoconiosis--Significance of subtight microscopic mineral particles. Am J
5521 Med 50:395-402, 1971

WCD 001407

5527 45. Alivisatos GP, Pontikakis AE, Terzis B: Talcosis of unusually rapid
5528 development. Br J Ind Med 12:43-49, 1955

5536 46. El-Ghawabi SH, El-Samra CH, Mahassab M: Talc pneumoconiosis. J Egypt
5538 Med Assoc 53:330-40, 1970

5546 47. Moskowitz RL: Talc pneumoconiosis--A treated case. Chest 58:37-41,
5547 1970

5554 48. Nam K, Gracey DR: Pulmonary talcosis from cosmetic talcum powder. J Am
5556 Med Assoc 221:492-93, 1972

5563 49. Mackey WA, Gibson JB: Siliceous granuloma due to talc--A cause of post-
5564 operative peritoneal adhesions. Br Med J 1:1077-78, 1968

5572 50. McCallum DI, Neil GS: Umbilical granulomata--With particular reference
5574 to talc granuloma. Br J Dermatol 83:151-56, 1970

5581 51. Tye MJ, Hashimoto K, Fox F: Talc granulomas of the skin. J Am Med

WCD 001408

WCD 001409

Assoc 198:1370-72, 1966

5589 52. McDermick EJ, Ramsey TL: Postoperative peritoneal granulomatous
5590 inflammation caused by magnesium silicate. J Am Med Assoc 116:817-21, 1941

5593 53. McLee ME Jr: Talc and cornstarch emboli in eyes of drug abusers. J Am
5600 Med Assoc 219:49-51, 1972

5607 54. Douglas FD, Kefilkoot KJ, Pate NL: Foreign particle emboliss in drug
5608 addicts--Respiratory pathophysiology. Ann Intern Med 75:835-72, 1971

5616 55. Honda K, Ishikawa Y, Shiba Y: [A case of papilloma of the conjunctiva
5617 caused by baby powder.] Folia Ophthalmol Jap 20:645-50, 1969 (Jap)

5624 56. Merliss RR: Talc treated rice and Japanese stomach cancer. Asian Med J
5626 19:29-32, 1972

5633 57. Matsuda M, Hodgkin MM, Tanaka A: Japanese gastric cancer--Potentially
5634 carcinogenic silicates (talc) from rice. Arch Pathol 97:366-68, 1974

5642 58. Hirohata T, Kuratsuka M: The geographical comparison of mortality from
5643 cancer of the stomach and ulcer of the stomach in Japan. Br J Cancer 23:465-
5645 79, 1969

5651 59. Pooley FD: Talc and gastric cancer. Arch Pathol Lab Med (Lett)
5653 100:110, 1976

5660 60. Stewart JM: Talc and gastric cancer. Arch Pathol Lab Med (Lett)
5662 100:110, 1976

5664 61. Haenszel W, Kurihara M, Segi M, Lee RKC: Stomach cancer among Japanese
5665 in Hawaii. J Natl Cancer Inst 49:969-88, 1972

5668 62. Henderson WJ, Joslin CAF, Turnbull AC, Griffiths K: Talc and carcinoma
5669 of the ovary and cervix. J Obstet Gynaecol Br Commonw 78:266-72, 1971

5677 63. Selikoff SG, Dement JM, Wagoner JK, Freiman JP: Mortality patterns among
5678 miners and millers of non-asbestiform talc. Presented before the Society for
5679 Occupational and Environmental Health Conference on Occupational Exposures to
5680 Fibrous and Particulate Dust and Their Extension into the Environment,
5681 Washington, D.C., Dec 6-7, 1977, 34 pp

5684 64. Katsnelson BA, Nakrasosova KA: Non-fibrous mineral dusts and malignent
5685 tumors. J Occup Med 21:15-20, 1979

5688 65. Rubino GF, Scansetti G, Piolatto G, Gay G: Mortality and morbidity
5689 among talc miners and millers in Italy. Presented before the Society for
5690 Occupational and Environmental Health Conference on Occupational Exposures to
5691 Fibrous and Particulate Dust and Their Extension into the Environment,
5693 Washington, D.C., Dec 6-7, 1977, 12 pp

5695 66. International classification of radiographs of pneumoconioses, rev.
5696 1968, Occupational Safety and Health Series No. 22. Geneva, International
5697 Labour Office, 1970, 24 pp

WCD 001410

5704 67. Fine LJ, Peters JM: Respiratory morbidity in rubber workers--I.
5706 Prevalence of respiratory symptoms and disease in curing workers. Arch
5707 Environ Health 31:5-9, 1976

5713 68. Hagman DN, Burgess WA, Peters JM: Talc Workers Health Study Report.
5714 Unpublished report submitted to NIOSH by DN Hagman of Harvard University,
5715 School of Public Health, Boston, Aug 1977, 52 pp

5718 69. Theriault GP, Peters JM, Fine LJ: Pulmonary function in granite shed
5719 workers of Vermont. Arch Environ Health 28:18-22, 1974

5722 70. Higgins ITT, Oliver JC, Ferris BG Jr, Peters ME, Campbell H, Higgins
5723 MK: IV. Chronic respiratory disease in an industrial town--A nine year
5725 follow-up study. Preliminary report. Am J Public Health 58:1667-1676

5728 71. Kassite J, Reddin S, Kleinfeld M: Pulmonary talcosis, a clinical and
5729 environmental study. AMA Arch Ind Health 20:408-13, 1959

5732 72. Kleinfeld M, Kassite J, Shapiro J, Kooyman C, Skencicki M: Lung
5733 function in talc workers--A comparative physiologic study of workers exposed
5734 to fibrous and granular talc dusts. Arch Environ Health 9:559-66, 1964

5741 73. Kleinfeld M, Kassite J, Kooyman C, Zaki MM: Mortality among talc miners
5742 and millers in New York State. Arch Environ Health 14:863-67, 1967

5750 74. Kleinfeld M, Kassite J, Zaki MM: Mortality experiences among talc
5751 workers--A follow-up study. J Occup Med 16:345-49, 1974

5754 75. Schaver AP, Zwicker CM, Cannon WC, Watson CR, Carlton WW: Inhalation of
5755 talc baby powder by hamsters. Food Cosmet Toxicol 15:21-29, 1977

WCD 001411

5763 76. Rehner JC, Gerry G, Cooke TJ, Hill MF, Pooley FD, Skidmore J: Animal
5764 experiments with talc. In Walton WH (ed): Inhaled Particles IV--Proceedings
5765 of an International Symposium Organized by the British Occupational Hygiene
5766 Society, Edinburgh, 22-26 September 1975. New York, Pergamon Press, 1977, pp
5767 647-64

5772 77. Sethge-Iwanska J: [Pathomorphological changes in the respiratory system
5773 in experimental talcosis.] Med Pr 22:45-57, 1971 (Pol)

5780 78. Schepers GWH, Durkan TM: An experimental study of the effects of talc
5781 dust on animal tissue. AMA Arch Ind Health 12:317-28, 1955

5784 79. Gross P, deTreville RTP, Crellin EJ, Grenquist MT, Pundsack FL: The
5785 pulmonary response to fibrous dusts of diverse compositions. Am Ind Hyg Assoc
5787 J 31:125-32, 1970

5792 80. Gerson MM: Dusting powder granuloma following surgery. Surg Gynec
5794 Obst 76:501-07, 1943

5801 81. Odell RT, Key JA, Taylor LN: The prevention of peritoneal adhesions and
5802 talc granulomata by cortisone. Surg Forum, 1951, pp 524-31

5805 82. Graham JDP, Jenkins ME: The effects of introducing certain suggested
5806 substitutes for talc into the peritoneal cavity and into wounds in
5808 experimental animals. J Pharm Pharmacol 4:392-98, 1952

5814 83. Rehner AP, Wilkerson CL, Cannon WC, Buschbom RL, Tanner FM: Pulmonary
5815 deposition, translocation and clearance of inhaled neutron-activated talc in
5816 hamsters. Food Cosmet Toxicol 15:213-24, 1977

WCD 001412

5823 84. Aehner AP, Tanner TA, Buschbom RL: Absorption of ingested talc by
5824 hamsters. Food Cosmet Toxicol 15:453-55, 1977

5832 85. Phillips JC, Young PJ, Hardy K, Gangolli SD: Studies on the absorption
5833 and disposition of 3H-labelled talc in the rat, mouse, guinea-pig and rabbit.
5835 Food Cosmet Toxicol 16:151-53, 1978

5837 86. Pott F, Friedrichs KH, Huth F: [Results from animal experiments on the
5838 carcinogenic activity of fibrous dusts and their interpretation in regard to
5840 tumorigenesis in humans.] Zentralbl Bakteriol Parasitenkd Infektionskr Hyg
5841 Abt [Orig Reihe B 162:467-505, 1976 (Ger)

5845 87. Selikoff IJ: Experimental studies on biological effects of tremolite talc
5847 on hamsters, in Goodwin A (ed.): Proceedings of the Symposium on Talc,
5849 Washington, D.C., May 8, 1973, Information Circular No. IC 8630. US Dept of
5850 the Interior, Bureau of Mines, 1974, pp 43-48

5852 88. Mutagenic Evaluation of Compound FDA 71-43--Talc. Springfield, VA, US
5854 Dept of Commerce, National Technical Information Service, 1974, 139 pp (NTIS
5855 PB 245 452)

5862 89. Teratologic Evaluation of FDA 71-43 (Talc). Springfield, VA, US Dept of
5863 Commerce, National Technical Information Service, 1973, 15 pp (NTIS PB 223
5864 628)

5871 90. Merenzano F, Coscia G, Tronzano L: [Epidemiology of silicosis in talc
5872 mines.] Med Lav 54:591-96, 1963 (Ita)

WCD 001413

5878 91. Anderson D, Ayer H, Beier E, Bolser JL, Ettinger H, Knight G, Kunkel
5879 K, Lynch P, Lynkin S, Lippmann M, Mercer T, Morse K: Guide for respirable
5880 dust sampling. Am Ind Hyg Assoc J 31:33-37, 1970

5887 92. Gardner LU: Reaction of the living body to different types of mineral
5888 dusts with and without complicating infection. Technical Publication No.
5890 929. New York, American Institute of Mining and Metallurgical Engineers Inc,
5891 1938. 15 pp

5896 93. Degueldre C: Dust Sampling in Mines. Occupational Safety and Health
5897 Series No. 9. Geneva, International Labour Office, 1967, 62 pp

5905 94. Warren PE: Evaluation of inhalation hazards based upon the respirable
5906 dust concept and the philosophy and application of selective sampling. Ind
5908 Hyg J 25:213-36, 1964

5914 95. Littlefield JB, Feicht FL, Schrenk HH: Bureau of Mines Midget Impinger
5915 for Dust Sampling. Report of Investigations No. 3360. US Dept of the
5917 Interior, Bureau of Mines, 1937, 7 pp

5923 96. Greenburg L, Bloomfield JJ: The Impinger dust sampling apparatus as
5924 used by the US Public Health Service. Public Health Rep 47:654-75, 1932

5932 97. Hatch T, Warren N, Drinker P: Modified form of the Greenburg-Smith

WCD 001414

impinger for field use, with a study of its operating characteristics. J Ind
5935 Hyg 14:301-11, 1932

5941 96. Kitto PH: Methods of dust measurement. In Orenstein AJ (ed.):
5944 Proceedings of the Pneumoconiosis Conference held at the University of
5945 Witwatersrand, Johannesburg, Feb 9-24, 1959. Boston, Little, Brown and Co,
5946 1960, pp 13-20

5950 97. Owens JS: Suspended impurity in the air. Proc R Soc London Ser A
5952 101:10-37, 1922

5959 100. Gurney SM, Williams CR, Ruigs RO: Investigation of the characteristics
5960 of the Bausch and Lomb dust counter. J Ind Hyg Toxicol 20:24-35, 1938

5968 101. Ray KH: The cascade impactor--An instrument for sampling coarse
5969 aerosols. J Sci Instrum 22:187-95, 1945

5977 102. Mercer TT: On the calibration of cascade impactors. Ann Occup Hyg 6:1-
5979 16, 1963

5986 103. Couchman JC: Use of cascade impactors for analyzing airborne particles
5987 of high specific gravity, in International Symposium on Fission Product
5989 Release and Transport Under Accident Conditions, Oak Ridge, Tenn, Apr 5-7,
5990 USAEC Report No. CONF-650407. Oak Ridge, US Atomic Energy Commission, 1965,
5991 vol 2, pp 1162-1203

WCD 001415

5993 104. Kaiser JL: Inertial and gravitational collectors, in Air Sampling
5995 Instruments for Evaluation of Atmospheric Contaminants, ed 4. Cincinnati,
5996 American Conference of Governmental Industrial Hygienists, 1972, pp 0-1 to 0-
5997 27

6002 105. Greenburg L, Smith GW: A new instrument for sampling aerial dust,
6003 Reports of Investigations Serial No. 2392. US Dept of the Interior, Bureau
6004 of Mines, 1922, 3 pp

6011 106. Drinker P, Hatch T: Industrial Dust--Hygienic Significance,
6012 Measurement, and Control, ed 2. New York, McGraw-Hill Inc, 1954, pp 147-55

6020 107. Mulryan HF: Characterization and occurrence of talc, in Goodwin A
6022 (ed.): Proceedings of the Symposium on Talc, Washington, D.C., May 8, 1973,
6023 Information Circular No. IC 8639, US Dept of the Interior, Bureau of Mines,
6024 1974, pp 16-21

6028 108. Determination of atmospheric concentration of fibrosis-producing and
6029 similar dusts--Proposed standard impinger sampling and counting technic, in
6030 Transactions of the Fifth Annual Meeting of the National Conference of
6031 Governmental Industrial Hygienists. Cincinnati, American Conference of
6032 Governmental Industrial Hygienists, Subcommittee on Standard Methods, 1942, 5
6033 pp

6037 109. Recommendations of the Medical Research Council Panels Relating to
6038 Selective Sampling, Minutes of Joint Meeting, London, Mar 14, 1952. Medical
6039 Research Council, Dust Subcommittee, Industrial Pulmonary Disease Committee,
6040 1952

6046 110. Lippmann M: "Respirable" dust sampling. Am Ind Hyg Assoc J 31:138-59,

WCD 001416

6052 111. Natch T, Newman WCL: Influence of particle size in dust exposure. J
6054 Ind Hyg Toxicol 30:172-80, 1948

6061 112. Davis CN: Dust sampling and lung disease. Br J Ind Med 9:120-26, 1952

6070 113. Watson HH: Dust sampling to simulate the human lung. Br J Ind Med
6072 10:93-100, 1953

6079 114. Free Silica (Quartz, Cristobalite, Tridymite) in Airborne Dust--
6080 Measurements Research Branch Analytical Method--Physical and Chemical
6081 Analysis Branch Method No. 259, in NIOSH Manual of Analytical Methods, ed 2,
6082 DHEW (NIOSH) Publication No. 77-157-A. Cincinnati, US Dept of Health,
6083 Education, and Welfare, Public Health Service, Center for Disease Control,
6084 National Institute for Occupational Safety and Health, 1977, vol 1, pp 259-1
6085 to 259-7

6087 115. Langer AM, Rohl AN, Wolff MS, Klimentidis R, Shirey SE: Review of
6088 current techniques for the analysis of fibers in talc, in Asher IM, McGrath
6089 PP (eds.): Symposium on Electron Microscopy of Microfibers--Proceedings of
6090 the First FDA Office of Science Summer Symposium. US Dept of Health,
6091 Education, and Welfare, Public Health Service, Food and Drug Administration,
6093 Office of Science, Bureau of Biologics, Bureau of Drugs, Bureau of Foods,
6094 1976, pp 28-33

6096 116. Diffractometric powder technique--Electrical characteristics of the
6097 diffractometer, in Klug HP, Alexander LE: X-Ray Diffraction Procedures for
6099 Polycrystalline and Amorphous Materials, ed 2. New York, John Wiley and Sons,
6100 1974, pp 330-35,614-15

WCD 001417

6104 117. Bertin EP: Principles and Practice of X-Ray Spectrometric Analysis, ed
6105 2. New York, Plenum Press, 1975, pp 181-83,289-95,903-45

6113 118. Crable JV, Knott MJ: Application of x-ray diffraction to the
6114 determination of chrysotile in bulk or settled dust samples. Am Ind Hyg
6115 Assoc J 27:383-87, 1966

6122 119. Crable JV, Knott MJ: Quantitative x-ray diffraction analysis of
6123 crocidolite and amosite in bulk or settled dust samples. Am Ind Hyg Assoc J
6124 27:469-73, 1966

6131 120. Keenan RG, Lynch JR: Techniques for the detection, identification and
6132 analysis of fibers. Am Ind Hyg Assoc J 31:567-97, 1970

6140 121. Nenadic CM, Crable JV: Application of x-ray diffraction to analytical
6141 problems of occupational health. Am Ind Hyg Assoc J 32:529-38, 1971

6148 122. Nenadic CM, Crable JV: Quantitative determination of talc and tremolite
6149 by x-ray diffraction. Cincinnati, US Dept of Health, Education, and Welfare,
6150 Public Health Service, Center for Disease Control, National Institute for
6151 Occupational Safety and Health, 23 pp (unpublished)

6157 123. Rohl AN, Langer AM: Identification and quantitation of asbestos in
6158 talc. Environ Health Perspect 9:95-109, 1974

WCD 001418

6166 124. Schelz JP: The detection of chrysotile asbestos at low levels in talc
6168 by differential thermal analysis. Thermochim Acta 8:197-204, 1974

6175 125. Sirkis LE, Fetsam E, Gilfrich JV, Johnson ET: Quantitative Analysis of
6176 Airborne Asbestos by X-ray Diffraction--Final Report on Feasibility Study.
6177 Springfield, Va, US Dept of Commerce, National Technical Information Service,
6178 1978, 13 pp (NTIS AD/A-007 530)

6185 126. Detection of Asbestiform Amphibole Minerals in Cosmetic Grade Talc,
6186 Method No. J4-1. Washington, DC, Cosmetic, Toiletry, and Fragrance
6187 Association, Standards Committee, Talc Subcommittee, 10 pp (undated)

6194 127. Pease DC: Introduction to electron microscopy, in Asher IM, McGrath PP
6196 (eds.):A Symposium on Electron Microscopy of Microfibers--Proceedings of the
6197 First FDA Office of Science Summer Symposium. US Dept of Health, Education,
6198 and Welfare, Public Health Service, Food and Drug Administration, Office of
6200 Science, Bureau of Biologics, Bureau of Drugs, Bureau of Foods, 1976, pp 44-
6201 47

6203 128. Zumwalde RD, Bement JM: Review and Evaluation of Analytical Methods for
6204 Environmental Studies of Fibrous Particulate Exposures, DHEW (NIOSH)
6205 Publication No. 77-204. Cincinnati, US Dept of Health, Education, and
6206 Welfare, Public Health Service, Center for Disease Control, National
6207 Institute for Occupational Safety and Health, Division of Surveillance,
6208 Hazard Evaluations, and Field Studies, 1977, 66 pp

6211 129. Siegel M, Smith AR, Greenburg L: The dust hazard in tremolite talc
6212 mining, including roentgenological findings in talc workers. Am J Roentgenol
6214 Radium Ther 49:11-29, 1943

6217 130. Criteria for a Recommended Standard--Occupational Exposure to
6218 Crystalline Silica, HEW Publication No. (NIOSH) 75-120. Cincinnati, US Dept
6220 of Health, Education, and Welfare, Public Health Service, Center for Disease

WCD 001419

Control, National Institute for Occupational Safety and Health, 1974, 121 pp

131. Kleinfeld M, Messite J, Langer AM: A study of workers exposed to asbestiform minerals in commercial talc manufacture. Environ Res 6:132-43, 1973

132. Talc Dust and Industrial Hygiene Survey--Plymouth Rubber Company, Canton, Massachusetts. Cincinnati, US Dept of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, 1972, 17 pp

133. Reevaluation of Control Measures in the Rubber Band Manufacturing Area--Plymouth Rubber Company, Canton, Massachusetts. Cincinnati, US Dept of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, 1973, 10 pp

134. Fundamentals Governing the Design and Operation of Local Exhaust Systems, ANSI Z9.2-1971. New York, American National Standards Institute Inc, 1971, 63 pp

135. Industrial Ventilation--A Manual of Recommended Practice, ed 15. Lansing, MI, American Conference of Governmental Industrial Hygienists, Committee on Industrial Ventilation, 1978, pp 1-1 to 14-8

136. Report of the Committee on Threshold Limits, in Proceedings of the 8th Annual Meeting of the American Conference of Governmental Industrial Hygienists, Chicago, Apr 7-13, 1946. Cincinnati, American Conference of Governmental Industrial Hygienists, 1946, p 55

137. Threshold Limit Values Adopted at April 1948 Meeting of the American Conference of Governmental Industrial Hygienists in Detroit, Michigan. Cincinnati, American Conference of Governmental Industrial Hygienists, 1948, 2 pp

WCD 001420

6280 139. Threshold Limit Values for 1962--Adopted at the 24th Annual Meeting of
6281 the American Conference of Governmental Industrial Hygienists, Washington,
6282 DC, May 13-15, 1962. Cincinnati, American Conference of Governmental
6283 Industrial Hygienists, 1962, pp 10-11

6289 139. Documentation of Threshold Limit Values. Cincinnati, American
6290 Conference of Governmental Industrial Hygienists, Committee on Threshold
6291 Limit Values, 1962, pp 97-99

6298 140. Ferro FN, Patton JR, Hobbs AA Jr: Pneumoconiosis in the talc industry.
6300 Am J Roentgenol Radium Ther 47:507-24, 1942

6306 141. Greenburg L: The dust hazard in tremolite talc mining. Yale J Biol Med
6308 19:481-501, 1947

6315 142. McLaughlin AIG, Rogers E, Dunham KC: Talc pneumoconiosis. Br J Ind Med
6317 6:184-94, 1949

6323 143. Jaques WE, Denirschka K: Pulmonary talcosis with involvement of the
6325 stomach and the heart--Report of a case. AMA Arch Ind Hyg 5:451-63, 1952

6332 144. Friedman PS, Bell MA, Solis-Cohen L: Talc pneumoconiosis. J Am Med

WCD 001421

Assoc 148:1418-19, 1952

6341 145. Mann E, Deasy JB: Talc pneumoconiosis in the textile industry. Br Med
6343 J 2:1460-61, 1954

6350 146. Hunt AC: Massive pulmonary fibrosis from the inhalation of talc.
6352 Thorax 11:287-94, 1956

6355 147. Hubner O, Muller G: [Mineralogical and physical-chemical investigations
6356 of talc silicosis and talc skin granulomas.] Arch Gewerbepathol Gewerbehyg
6358 15:440-46, 1957 (Ger)

6363 148. Seeler AO: Toxic hazards--Talc pneumoconiosis. N Engl J Med 261:1084-
6365 88, 1959

6372 149. Hague NL Jr, Mallette FS: A study of workers exposed to talc and other
6373 dusting compounds in the rubber industry. J Ind Hyg Toxicol 31:359-64, 1949

6380 150. Threshold Limit Values for 1964--Adopted at the 26th Annual Meeting of
6381 the American Conference of Governmental Industrial Hygienists, Philadelphia,
6382 Pennsylvania, April 25-28, 1964. Cincinnati, American Conference of
6383 Governmental Industrial Hygienists, 1964, pp 20-21

6387 151. Threshold Limit Values for 1967--Recommended and Intended Values.
6388 Cincinnati, American Conference of Governmental Industrial Hygienists, 1967,
6389 p 15

WCD 001422

6395 152. Documentation of Threshold Limit Values, rev ed. Cincinnati, American
6396 Conference of Governmental Industrial Hygienists, Committee on Threshold
6397 Limit Values, 1966, p 15

6400 153. Threshold Limit Values of Air-borne Contaminants [sic] for 1968 --
6401 Recommended and Intended Values. Cincinnati, American Conference of
6402 Governmental Industrial Hygienists, 1968, p 17

6404 154. Threshold Limit Values for Airborne Contaminants--Adopted by ACGIH for
6405 1969 and Intended Changes. Cincinnati, American Conference of Governmental
6406 Industrial Hygienists, 1969, pp 16-19

6413 155. TLV's--Threshold Limit Values for Substances [sic] in Workroom Air
6414 Adopted by ACGIH for 1972. Cincinnati, American Conference of Governmental
6415 Industrial Hygienists, 1972, pp 30-31,38-39

6421 156. TLVs--Threshold Limit Values for Chemical Substances and Physical
6422 Agents in the Workroom Environment with Intended Changes for 1974.
6423 Cincinnati, American Conference of Governmental Industrial Hygienists, 1974,
6424 pp 33-36,40-41

6430 157. Documentation of the Threshold Limit Values for Substances in Workroom
6431 Air with Supplements for These Substances Added or Changed Since 1971, ed 3,
6432 1971. Cincinnati, American Conference of Governmental Industrial Hygienists,
6433 Committee on Threshold Limit Values, 2nd printing, 1974, pp 242-45,262

6439 158. Schepers GWH, Durkan TM: The effects of inhaled talc-mining dust on the
6440 human lung. AMA Arch Ind Health 11:182-97, 1955

WCD 001423

6448 159. TLVs--Threshold Limit Values for Chemical Substances and Physical
6449 Agents in the Workroom Environment with Intended Changes for 1977.
6450 Cincinnati, American Conference of Governmental Industrial Hygienists, 1977.
6451 pp 32-39

6457 160. Occupational Exposure Limits for Airborne Toxic Substances--A Tabular
6458 Compilation of Values from Selected Countries. Occupational Safety and Health
6459 Series No. 37. Geneva, International Labour Office, 1977, pp 12-32,243-69

6466 161. Majewski C, Szulc H, Owczarek L, Majewski W: [A contribution to the
6467 pathogenesis of wire lungs.] Patol Pol 18:95-101, 1967 (Pol)

6474 162. Lee J, Sapira JD: Retinal and cerebral microembolization of talc in a
6475 drug abuser. Am J Med Sci 265:75-77, 1973

6483 163. Pask JA, Wagner WF: Fundamental studies of talc--I. Constitution of
6484 talcs. J Am Ceram Soc 37:118-28, 1954

6491 164. Steeple IS, Brindley GW: A structural study of talc and talc-tremolite
6492 relations. J Am Ceram Soc 43:34-42, 1960

WCD 001424

IX. APPENDIX I

SAMPLING AND ANALYTICAL METHOD FOR TALC (RESPIRABLE DUST)

The following is a generalized method for determining the concentration of mass respirable dust in air known to be contaminated by talc as defined in Chapter I: this method is non-specific for talc.

Principle of the Method

(a) A known volume of air is drawn at a flowrate of 1.7 liters/minute through polyvinyl chloride filters (pre-weighed) preceded by 10 mm nylon cyclone separators to collect respirable dust.

(b) The sample-containing filters are removed from the cassette, and weighed with a suitable microbalance.

Range and Sensitivity

With a good microbalance, the lower limit of the working range should be approximately 0.05 mg/sample. There is no upper limit unless the filter is completely overloaded.

Interferences

The presence of any other particulate material in the air being sampled will be a positive interference, since this is a gravimetric method.

Advantages and Disadvantages

WCD 001425

The recommended method is simple, inexpensive, and requires no bulky equipment. However, it is not specific for talc.

Apparatus

(a) Sampling Equipment—a sampling unit for the collection of personal air samples for the determination of respirable talc dust having the following components:

(1) A 10-mm nylon cyclone separator with a bracket for securing the filter cassette

(2) A filter unit, consisting of a 37-mm polyvinyl chloride or Millipore filter with a 0.6-(u)m pore size, a support pad, shrink band, and a three-piece filter cassette

(3) A calibrated personal sampling pump whose flow can be determined to an accuracy of ±5% at the recommended flowrate of 1.7 liters/minute; the pump must be calibrated with a filter holder and filter in the line.

(b) Thermometer

(c) Manometer

(d) Stopwatch

(e) Soapbubble meter

(f) A plastic petri dish used as a filter holder for storage, conditioning, and weighing

(g) Analytical Equipment - a microbalance capable of weighing to 0.01 mg

(h) Balance room of controlled temperature and relative humidity

Procedure

WCD 001426

(a) Preparation of Filters. All filters must be conditioned and weighed before use. Filters must be equilibrated in the balance room at least 1 hour prior to weighing.

(b) Sampling Requirements

(1) To collect respirable dust, use a personal sampling pump to pull air through a cyclone preseperator and a polyvinyl chloride filter. The filter holder is held together by the cyclone bracket and is directly connected to the outlet of the cyclone preseperator. A piece of flexible tubing is used to connect the filter holder to the pump. Fasten the sampler to the lapel or shirt front, and start the pump to draw air through the sampler at a flowrate of 1.7 liters/minute. After sampling, the filter cassettes are removed from the cyclone and sealed by replacing the small plugs at both ends.

(2) With each batch of 10 samples, submit 1 filter from the same lot as that used for sample collection. This filter should be handled in exactly the same way as the samples, except that it should not be exposed to the workplace environment. Label this as a blank.

(c) Shipping of Samples. The filter cassettes should be shipped in a suitable container designed to prevent damage to the filter in transit.

(d) Analysis of Samples

(1) If the outer surface of the cassette filter holder is heavily coated with dust, carefully swab it with a moist paper towel before opening the cassette to minimize sample contamination. Discard the paper towel.

(2) Open the cassette filter holder and carefully remove the filter from the supporting pad in the holder with the aid of filter tweezers.

WCD 001427

Transfer filters to a petri dish.

(3) Weigh the filter with a microbalance.

Calibration and Standards

The microbalance should be properly zeroed for all weighings, and preferably the same microbalance should be used for weighing each filter before and after samples are collected.

Calibration of Sampling Trains

The accurate calibration of the sampling pump is essential for the correct interpretation of the volume indicated. The proper frequency of calibration is dependent on how the pump is used, cared for, and handled. Pumps should be recalibrated if they have been subjected to misuse or if they have just been repaired or received from a manufacturer. If the pump receives hard usage, more frequent calibration may be necessary. Maintenance and calibration should be performed regularly and records should be kept.

Ordinarily, pumps should be calibrated in the laboratory before they are used in the field, during field procedures, and after they have been used to collect a large number of field samples. The accuracy of calibration is dependent on the type of instrument used as a reference. The choice of calibration instrument will depend largely on where the calibration is to be performed. For laboratory testing, a soapbubble meter or spirometer is recommended, although other standard calibrating instruments, such as a wet-test meter or dry-gas meter, can be used.

Instructions for calibration with the soapbubble meter follow. If another

WCD 001428

calibration device is selected, equivalent procedures should be used. Since the flowrate given by a pump is dependent on the pressure drop of the sampling device, in this case a polyvinyl chloride filter, the pump must be calibrated while operating with the representative filters in line. Calibration of the sampling train should be performed at local pressure and calculated for 1 atmosphere.

(a) While the pump is running, check the voltage of the pump battery with a voltmeter to assure adequate voltage for calibration. Charge the battery if necessary.

(b) Place the preweighed filter in the filter cassette.

(c) Assemble the sampling train according to the manufacturer's specifications or as shown in Figure XI-1.

(d) Turn on the pump and moisten the inside of the soapbubble meter by immersing the buret in the soap solution. Draw bubbles up the inside until they are able to travel the entire buret length without bursting.

(e) Adjust the pump rotameter to provide a flowrate of 1.7 liters/minute.

(f) Start a soapbubble up the buret and measure with a stopwatch the time it takes the bubble to pass through a minimum of 1.0 liter.

(g) Repeat the procedure in (f) at least three times, average the results, and calculate the flowrate by dividing the volume of air between the preselected marks by the time required for the soapbubble to traverse the distance.

(h) Record the following calibration data: volume measured, elapsed time, air temperature, atmospheric pressure, serial number of the pump, and name of the person performing the calibration.

WCD 001429

6711 Calculations

6714 (a) Record the tare weight, in fulg, of the filter before sampling.

6717 (b) Record the weight, in fulg, of the filter containing the sample.

6720 (c) The difference between these two weights represents the weight of the

6721 sample in fulg.

6723 (d) Correct each sample weight by subtracting the weight obtained for the

6725 blank.

6727 (e) Convert volume of air sampled to standard conditions of 25 C and 760

6728 mmHg*

$$Vs = V \times \frac{P}{760} \times \frac{298}{(T + 273)}$$

6732 where*

6734 Vs = volume of air in liters at 25 C and 760 mmHg.
6735 V = volume of air in liters as measured.
6736 P = barometric pressure in mmHg.
6737 T = ambient air temperature in degrees C.

6741 (f) Express concentration of talc in the air sampled in mg/cu m (fulg per

6742 liter = mg/cu m)*

$$mg/cu\ m = \frac{\text{talc found}}{Vs}$$

WCD 001430

X. APPENDIX II

SAMPLING AND ANALYTICAL METHOD FOR ASBESTOS FIBERS ASSOCIATED WITH TALC DUST IN AIR

This method is recommended for use after a phase contrast counting procedure [1146] has determined that the respirable airborne dust contains >0.1 fibers/cc. It is intended that with this method, the concentration of amphibole fibers in air can be determined. This method is adapted from a NIOSH report [128] and an EPA Provisional Methodology Manual [12].

Principle of the Method

A known volume of air is drawn through a membrane filter. The fibers and dust particles collected on the filter are fused to a microscopically smooth surface, vacuum-coated with carbon and transferred to a carbon-coated electron microscope grid. The grid is then analyzed by transmission electron microscopy with selected area electron diffraction techniques (SAED) for identification and counting of asbestos fibers.

Range and Sensitivity

With this method, a minimum of 10 grid openings is to be counted. If 1 fiber is found in 10 grid openings, the detection limit is about 0.02 fiber/cc.

WCD 001431

6784 Interferences

6787 The identification procedure for asbestos fibers is accurate so long as a
6788 recognizable electron diffraction pattern can be obtained. Contaminants of
6789 the fiber, interference from nearby particles, fibers that are too small or
6789 too thick, and non-suitable orientation of the fiber could effect the
6791 formation of an electron diffraction pattern.

6794 Precision and Accuracy

6797 The precision and accuracy of this method has not been determined.

6801 Advantages and Disadvantages

6804 The combined method of selected area electron diffraction and transmission
6805 electron microscopy gives a positive identification of amphibole fibers in a
6806 sample of mixed minerals. Visual characterization of particulate morphology
6807 and simultaneous observation of the single-fiber selected area electron
6808 diffraction pattern can be done. The specific chemical composition of
6809 amphibole fibers is not determined by this method. Special care is required
6810 in sample preparation and typical analysis of sample may take 90 minutes to 2
6811 hours.

6814 Apparatus

6816 (a) Sampling Equipment

6818 The sampling unit for collection of personal dust samples for determining
6819 the presence of asbestos fibers associated with talc dust has the following
6820 components:

WCD 001432

(1) The filter unit, consisting of a 37-mm polyvinyl chloride or Millipore membrane filter, filter support pad, and a three-piece cassette filter holders

(2) A calibrated personal sampling pump whose flow can be determined to an accuracy of ±5% at the recommended flowrate of 1.7 liters/minute.

(b) Analytical Equipment

(1) Transmission or transmission/scanning electron microscope

(2) Vacuum evaporator for carbon-coating of fused filter

(3) Carbon tip, 5 mm in length and 1 mm in diameter

(4) Petri dish

(5) Whatman filter

(6) Electron microscope grid, 200-mesh

(7) Cork bore, scalpel, and tweezers

(8) Glass slide

(c) Reagents

(1) Acetone

(2) Formvar

(d) Calibration Equipment

(1) Thermometer

(2) Manometer

(3) Stopwatch

(4) Soapbubble meter

Procedure

(a) Sampling

WCD 001433

(1) Place a membrane filter in a three-piece filter cassette or holder. Connect the holder and the personal sampling pump with flexible tubing. Mount the pump to the worker's belt and clip the filter holder to the lapel or shirt front as close to the breathing zone as is practicable.

(2) Remove the top cover of the plastic filter holder, then invert the holder making certain the exposed filter is facing downward. Turn the pump on and set the flowrate at 1.7 liters/minute.

(3) After sampling, replace the plastic top cover and the small end plug. Keep the filters in their holder and prepare them for shipment to a laboratory for analysis.

(4) With each batch of 20 samples, submit to the laboratory, one filter from each batch of the filters for a blank count. The blank filters should be given the same handling treatment as those used to collect air samples, except that the blanks should not be exposed.

(b) Sample Preparation

(1) Cut out a section of the filter with an 8-mm diameter cork bore or a scalpel.

(2) Remove the cut-out section and place it, sample side up, on a clean microscope slide. Use a gummed binder ring to fasten the circular section of filter to the slide, or use a thin strip of transparent tape to fasten the scalpel-cut section.

(3) Put four Whatman filters in a covered petri dish and saturate them with acetone. Place the slide assembly on top of the acetone-saturated filters for 2-15 minutes to dissolve away the microporous structure of the membrane filter. This will produce a fused and microscopically smooth surface

WCD 001434

on the sample side of the membrane filter.

(a) After the filter has been fused, place the slide assembly in a vacuum evaporator on a rotary stage, where the sampled side of the filter is to be coated with carbon. The tip of the carbon rod should be placed perpendicular to, and approximately 10 cm from, the center of the filter section. Evaporate a light coating of carbon onto the filter.

(5) Place four Whatman filters in a petri dish. Put several 200-mesh formvar/carbon-coated electron microscope grids right side up on the Whatman filters.

(6) Cut sections somewhat larger than the grids from the coated membrane filter and place, sample side down, on the electron microscope grid. Carefully saturate the Whatman filter with acetone by adding acetone dropwise along the edge of the petri dish. The acetone should never permeate above the surface of the top of the Whatman filter.

(7) Let the membrane filter-grid-Whatman filter assembly stand for 8-16 hours for complete dissolution of the filter matrix by the acetone vapor. Saturation of Whatman filters should be maintained for this period. After this step, only the particulates adhering to the carbon film are left on the grids.

(c) Identifying and Counting Asbestos Fibers

(1) Place the prepared grid with the sample on it in the transmission electron microscope.

(2) Scan the grid to assure even distribution of particulates and to ascertain the quality and suitability of the sample preparation. If complete clearing of the filter substrate had not taken place, then repeat step (b) for

WCD 001435

an additional 4-6 hours. Select a proper magnification for observation.

(3) Perform selected area electron diffraction analysis on particulates having a length-to-width ratio of greater than or equal to 3:1. Determine which fiber has a positive amphibole diffraction pattern, positive chrysotile diffraction pattern, nonasbestos diffraction pattern, ambiguous pattern, or no SAED pattern.

(4) Size the identified fiber with calibrated circles or millimeter markings etched on the viewing screen.

(5) Take and store selected pictures of SAED patterns for later reference.

(6) Calculate fiber concentrations using the average grid opening area as the counting field area. To optimize statistical accuracy of the analysis, 10 grid openings or 50 fibers should be counted and analyzed from each sample, with a minimum of 5 grid openings analyzed.

(d) Calibration and Standards

Although the UICC (Union International Contre le Cancer) standards can be used for calibration purposes, the bulk minerals from which talc is used in a workplace is a more reliable standard. Therefore, bulk quantities of the sampled minerals should be obtained and characterized.

(e) Calibration of Sampling Trains

The accurate calibration of a sampling pump is essential for the correct interpretation of the values indicated. The proper frequency of calibration is dependent on how the pump is used, cared for, and handled. Pumps should be recalibrated if they have been misused or if they have just been repaired or received from a manufacturer. If the pump receives hard usage, more frequent

WCD 001436

6992 calibration may be necessary. Maintenance and calibration should be performed
6993 regularly and records should be kept.
6995 Ordinarily, pumps should be calibrated in the laboratory both before they
6996 are used in the field, during field procedures, and after they have been used
6997 to collect a large number of field samples. The accuracy of calibration is
6998 dependent on the type of instrument used as a reference. The choice of
6999 calibration instrument will depend largely on where the calibration is to be
7001 performed. For laboratory testing, a soapbubble meter or spirometer is
7002 recommended, although other standard calibrating instruments, such as a wet-
7003 test meter or dry-gas meter, can be used.
7005 Instructions for calibration with the soapbubble meter follow. If another
7006 calibration device is selected, equivalent procedures should be used. Since
7007 the flowrate given by a pump is dependent on the pressure drop of the sampling
7008 device, in this case a membrane filter, the pump must be calibrated while
7010 operating with the representative filter in line. Calibration of the sampling
7011 train should be performed at local pressure and calculated for 1 atmosphere.
7014 (1) While the pump is running, check the voltage of the pump battery
7015 with a voltmeter to assure adequate voltage for calibration. Charge the
7016 battery if necessary.
7018 (2) Place a filter in the filter cassette.
7021 (3) Assemble the sampling train according to the manufacturer's
7022 specifications or as shown in Figure XI-1.
7024 (4) Turn on the pump and moisten the inside of the soapbubble meter
7025 by immersing the buret in the soap solution. Draw bubbles up the inside until
7026 they are able to travel the entire buret length without bursting.

WCD 001437

(5) Adjust the pump rotameter to provide a flowrate of 1.7 liters/minute.

(6) Start a soapbubble up the buret and measure with the stopwatch the time it takes the bubble to pass through a minimum of 1.0 liter.

(7) Repeat the procedure in (6) at least three times, average the results, and calculate the flowrate by dividing the volume of air between the preselected marks by the time required for the soapbubble to traverse the distance.

(8) Record the following calibration data: volume measured, elapsed time, air temperature, atmospheric pressure, serial number of the pump, date, and name of the person performing the calibration.

Calculation

(a) Record the number of asbestos fibers identified and counted, in both the sampled and blank filters.

(b) Record the number of grid openings counted, in both the sampled and blank filters.

(c) Convert volume of air sampled to standard conditions of 25 C and 760 mmHg

$$V_s = V \times \frac{P}{760} \times \frac{298}{(T + 273)}$$

where:

V_s = Volume of air sampled in liters at 25 C and 760 mmHg

V = Volume of air in liters as sampled

P = Barometric pressure in mmHg

WCD 001438

7065 T = ambient air temperature in C

7066 (d) The concentration of asbestos fibers in air samples can be calculated

7069 from:

$$AC = \frac{\left[\left(\frac{FC}{N}\right) - \left(\frac{FB}{B}\right)\right] \times EA}{Vs \times A \times 1000}$$

7073 where:

7074 AC = Asbestos fiber concentration in air, number of fibers/cc

7075 FC = total number of asbestos fibers counted in sample grids

7076 N = total number of grid openings counted for sample

7077 FB = total number of asbestos fibers counted in blank

7078 B = total number of grid openings counted for blank

7079 A = average area of grid opening, sq mm

7080 EA = Effective area of the filter, sq mm

7081 Vs = Volume of air sampled in liters at 25 C and 760 mmHg

WCD 001439

XI. TABLE AND FIGURE

TABLE XI-1

SUMMARY OF CHEMICAL, PHYSICAL AND MINERALOGICAL PROPERTIES OF TALC

Empirical formula	$3MgO\ 4SiO_2\ H_2O$
Formula weight	63.5% SiO_2, 31.7% MgO, 4.8% H_2O
Appearance	Platy, soft, exhibiting a high degree of lubricity (slip) to fibrous, hydrophobic surface properties, slippery feel
Mohs scale of hardness	1, maybe harder with impurities
Color	Snow-white (pure) to greenish grey and various shades of green (with impurities)
Specific gravity	2.58-2.83
X-ray unit cell dimensions	a=5.27±0.03a.u. b=9.13±0.03a.u. c=18.88±0.05a.u. β=100°15'±15'
DTA endothermic peak (Differential Thermal Analysis)	965 C
Refraction index	1.54-1.59
Crystal form	Foliated, lamellar, fibrous, or massive
Crystalline structure	Lamellar, brucite sheet between two silica sheets, forming talc layers superimposed indefinitely. All layers are electrically neutral and are held together by van der Waal's forces

Adapted from References [6,163,164,1]

WCD 001440

WCD 0014411

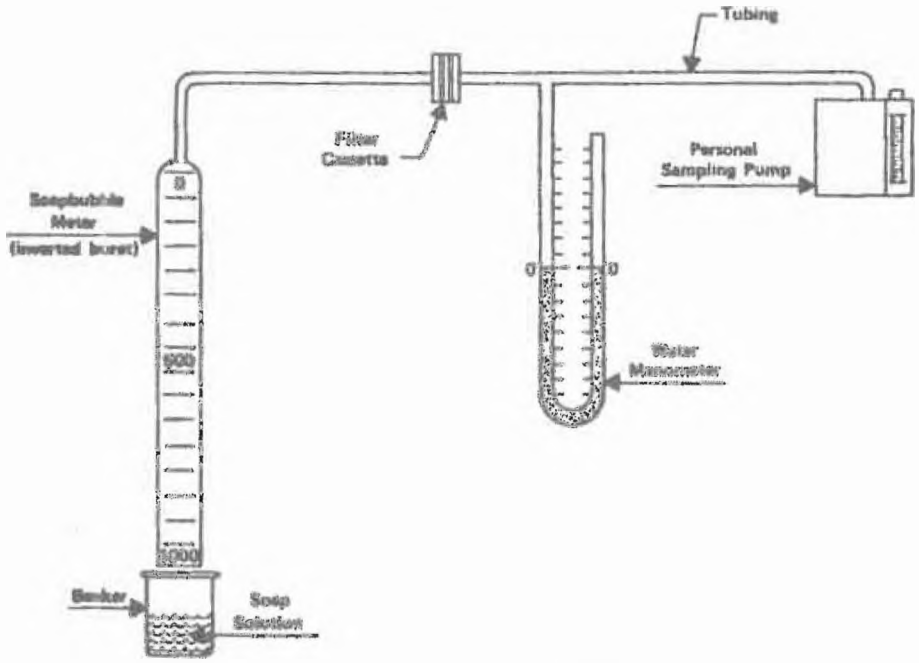


FIGURE XI-1

CALIBRATION SETUP FOR PERSONAL SAMPLING WITH FILTER CASSETTE

5 TC CONVERSION LIST

SEQ #.	REF #.
0001	#TC 686
0002	#TC 227
0003	#TC 496
0004	#TC 58
0005	#TC 815
0006	#TC 679
0007	#TC 33
0008	#TC 731
0009	#TC 664

WCD 001442

18	0010	#TC	801
19	0011	#TC	702
20	0012	#TC	832
21	0013	#TC	9
22	0014	#TC	111
23	0015	#TC	776
24	0016	#TC	278
25	0017	#TC	660
26	0018	#TC	807
27	0019	#TC	806
28	0020	#TC	715
29	0021	#TC	333
30	0022	#TC	607



32 00.28 #IC 524

WCD 001444

33 0025 #TC 265

34 0026 #TC 481

35 0027 #TC 242

36 0028 #TC 72

37 0029 #TC 217

38 0030 #TC 165

39 0031 #TC 15

40 0032 #TC 110

41 0033 #TC 14

42 0034 #TC 307

43 0035 #TC 79

44 0036 #TC 41

45 0037 #TC 269

46 0038 #TC 12

47 0039 #TC 31

48 0040 #TC 80

49 0041 #TC 116

50 0042 #TC 162

51 0043 #TC 76

52 0044 #TC 158

53 0045 #TC 169

54 0046 #TC 6

55 0047 #TC 440

56 0048 #TC 160

WCD 001445

59 005 I ● TC 206

```
60 0052    #TC  594
61 0053    #TC  174
62 0054    #TC  259
63 0055    #TC  198
64 0056    #TC  645
65 0057    #TC  144
66 0058    #TC  821
67 0059    #TC  778
68 0060    #TC  157
69 0061    #TC  718
70 0062    #TC  830
71 0063    #TC  777
72 0064    #TC  588
73 0065    #TC  118
74 0066    #TC  800
75 0067    #TC  791
76 0068    #TC  792
77 0069    #TC   29
78 0070    #TC  211
79 0071    #TC  192
80 0072    #TC   40
81 0073    #TC  134
82 0074    #TC  336
83 0075    #TC  295
84 0076    #TC  277
85 0077    #TC    3
86 0078    #TC  466
```

WCD 001447

87	0079	#TC	766
88	0080	#TC	408
89	0081	#TC	132
90	0082	#TC	280
91	0083	#TC	793
92	0084	#TC	295
93	0085	#TC	60
94	0086	#TC	335
95	0087	#TC	488
96	0088	#TC	26
97	0089	#TC	119
98	0090	#TC	659
99	0091	#TC	652
100	0092	#TC	653
101	0093	#TC	647
102	0094	#TC	648
103	0095	#TC	649
104	0096	#TC	655
105	0097	#TC	656
106	0098	#TC	728
107	0099	#TC	724
108	0100	#TC	725
109	0101	#TC	727
110	0102	#TC	729
111	0103	#TC	657
112	0104	#TC	651
113	0105	#TC	58

WCD 001448

114	0106	@TC	734
115	0107	@TC	730
116	0108	@TC	663
117	0109	@TC	732
118	0110	@TC	735
119	0111	@TC	736
120	0112	@TC	700
121	0113	@TC	681
122	0114	@TC	682
123	0115	@TC	721
124	0116	@TC	722
125	0117	@TC	723
126	0118	@TC	13
127	0119	@TC	291
128	0120	@TC	500
129	0121	@TC	225
130	0122	@TC	733
131	0123	@TC	737
132	0124	@TC	703
133	0125	@TC	831
134	0126	@TC	720
135	0127	@TC	43
136	0128	@TC	716
137	0129	@TC	63
138	0130	@TC	104
139	0131	@TC	107
140	0132	@TC	827

```
141 0133    #TC  829
142 0134    #TC  618
143 0135    #TC  619
144 0136    #TC  620
145 0137    #TC  621
146 0138    #TC   81
147 0139    #TC  269
148 0140    #TC   70
149 0141    #TC  290
150 0142    #TC  209
151 0143    #TC  388
152 0144    #TC   47
153 0145    #TC  363
154 0146    #TC  387
155 0147    #TC   46
156 0148    #TC  622
157 0149    #TC  623
158 0150    #TC  802
159 0151    #TC  803
160 0152    #TC  624
161 0153    #TC  628
162 0154    #TC  631
163 0155    #TC  629
164 0156    #TC.  276
165 0157    #TC  630
166 0158    #TC  632
167 0159    #TC  216
```

WCD 001450

168 0160 @TC 127
169 0161 @TC 78
170 0162 @TC 77

WCD 001451