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HEALTH ASSESSMENT DOCUMENT FOR VERMICULITE

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PREFACE

This health assessment on vermiculite was prepared for the Office of Health and Environmental Assessment to serve as a source document for EPA use. In the development of the assessment document, the scientific literature has been inventoried, key studies have been evaluated, and summary/conclusions have been prepared so that the chemical's toxicity and related characteristics are qualitatively identified. Observed effect levels and other measures of dose-response relationships are discussed, where appropriate, so that the nature of the adverse health responses is placed in perspective with observed environmental levels. The relevant literature for this document has been reviewed through early 1991.

Any information regarding sources, emissions, ambient air concentrations, and public exposure has been included only to give the reader a preliminary indication of the potential presence of this substance in the ambient air. While the available information is presented as accurately as possible, it is acknowledged to be limited and dependent in many instances on assumption rather than specific data. This information is not intended, and, therefore, should not be used, as an exposure assessment by which to estimate risk to public health.

1. SUMMARY

Concern surrounding the adverse health effects of asbestos on the general population stimulated interest in the potential health effects of other related minerals and man-made fibers. One of these is vermiculite, a nonfibrous silicate mineral with multiple consumer uses that has been shown to contain various concentrations of asbestiform fibers. The health effects of vermiculite are discussed in this document.

Vermiculite (CAS No. 1318-00-9) is a micaceous hydrate of magnesium−iron−aluminum silicates. Vermiculite crystals are composed of two silicate layers connected by a hydrous layer. The chemical composition of vermiculite is $(Mg,Fe,Al)_3(Al,Si)_4O_{10}(OH)_2 \bullet 4H_2O$. It is unique among minerals in its ability to exfoliate or expand up to 20 times its original size at high temperatures. It has high-cation-exchange capacity and a very low thermal conductivity. About 275,000 metric tons were produced in the United States in 1988. Most of the vermiculite mined and beneficiated is exfoliated and used in construction aggregates, insulation, and agricultural applications.

It has been estimated that approximately 802×10^3 kg of vermiculite were released into the air, $89{,}900 \times 10^3$ kg were released into water, and 2.490×10^3 kg were released as solid waste in 1979 based on a production volume of 1 million tons (1.2×10^9 kg). Exposure to vermiculite occurs mainly via the inhalation route; ingestion and dermal absorption are not significant routes of exposure. However, exposure to asbestos in the occupational environment or from ambient air near point sources is of concern. Prior to 1973, occupational exposures to asbestos fibers ranged from 0.049 fibers/cm^3 to 1.511 fibers/cm^3 for an 8-h, time-weighted average (TWA) for workers in a vermiculite-processing company. Miners' exposure to tremolite from a vermiculite mine in Montana ranged from the highest dust concentrations of 101.5 to 124.9 fibers/cm^3 prior to 1970 to a low of 22.1 to 27.1 fibers/cm^3 after 1970. At a mining and milling operation in Montana, prior to 1964, exposure estimates for various jobs ranged from 13 to 182 fibers/cm^3. Exposure estimates decreased greatly and were $<$1.0 fiber/cm^3 in most areas from 1977 to 1982. Based on samples taken by the company in 1984, the average 8-h TWA exposure was 0.1 fibers/cm^3. The National Occupational Hazard Survey (1976) reports that 104,456 workers were potentially exposed to vermiculite from 1972 to 1974, whereas the National Occupational Exposure Survey (1984) estimated that 4,293 workers, including 365 females, were exposed to vermiculite in 1980.

Nonoccupational exposure to vermiculite is high. In 1979, approximately 13 million persons were estimated to have been exposed to vermiculite near exfoliation plants in the United States. In addition, about 106 million persons were exposed to consumer products containing vermiculite.

Ambient levels of asbestos fibers in the vicinity of vermiculite mines and mills have been reported to range from 0.5 fibers/cm^3 (4.5 km from a mine) to 0.02 fibers/cm^3 (50 m from a mine).

Vermiculite is not expected to undergo chemical transformation when released into the environment. Analytical procedures used to identify vermiculite are the membrane filter, analysis of samples by polarized light microscopy with dispersion staining, phase-contrast light microscopy, scanning electron microscopy using energy dispersive x-ray analysis and transmission electron microscopy, optical microscopy, and x-ray diffraction.

No information is available on the retention, biodisposition, or clearance of vermiculite following oral administration or inhalation exposure. However, several studies of miners and millers suggest that vermiculite may be inhaled, deposited, and retained in the lungs. No information was found on the acute, subchronic, or chronic toxicity of vermiculite. Female Sprague-Dawley rats injected intrapleurally with 25 mg of vermiculite developed granulomas in the lungs and viscera. However, no tumors were observed after 104 weeks. Genotoxicity and cytotoxicity studies were not found in the available literature. Similarly, teratogenicity and reproductive effects studies were not found.

An association between previous vermiculite exposure and parenchymal and pleural radiographic abnormalities has been found in three cross-sectional morbidity studies of miners and millers. Although these changes did not correlate with pulmonary function tests, they did correlate with age and fiber-years. However, the vermiculite contained fibrous tremolite—actinolite. A historical prospective mortality study of one of the mining and milling facilities indicated a significant twofold excess in mortality for lung cancer and nonmalignant respiratory disease (NMRD), especially in the highest exposure category and among those cases with a latency period of greater than or equal to 20 years.

Similar results were observed in another historical prospective mortality study of the same mine and mill. It was concluded that the workers in this facility had a serious hazard from lung cancer, pneumoconiosis, and mesothelioma. However, the presence of tremolite–actinolite asbestos precludes concluding that there is a direct relationship between exposure to vermiculite and lung cancer or NMRD.

Consequently, the weight of evidence from data for human health effects and animal toxicity is inadequate to characterize the carcinogenic potential of vermiculite. Similarly, human health effects and animal toxicity data are inadequate to characterize noncarcinogenic effects associated with vermiculite exposure.

However, the weight of evidence for asbestos-contaminated vermiculite is sufficient to show a causal relationship for increased lung cancer in miners and millers.

2. BACKGROUND INFORMATION

2.1 PHYSICAL AND CHEMICAL PROPERTIES

Vermiculite (CAS No. 1318-00-9) is a micaceous hydrate of magnesium−iron−aluminum silicates. The chemical composition of vermiculite varies, but an acceptable general formula is $(Mg,Fe,Al)_3(Al,Si)_4O_{10}(OH)_2 \bullet 4H_2O$ (Bates and Jackson, 1980). Vermiculite crystals can be colorless, pale brown, or brownish-green depending upon the metallic base, and are composed of two silicate layers connected by a hydrous layer. The thickness of the unit cell in fully hydrated materials is about 14 Å (Gruner, 1934). Vermiculite is composed of monoclinic, plate-like crystals that exhibit perfect (001) basal cleavage.

Vermiculite has a specific gravity of 2.6 g/cm^3, a melting point of 1,315 °C, and a significant capacity for reversible cation exchange. All of the major commercial deposits occur in ultramafic and mafic host rocks. The material that is mined is mixed-layer vermiculite−biotite and vermiculite−phlogopite (silicate materials). Other minerals commonly present in the deposits include quartz, feldspar, apatite, corundum, chlorite, asbestos, talc, and clays. The main commercial mining deposits of vermiculite are located in Montana, Virginia, and South Carolina, as well as in South Africa (Dixon et al., 1985).

Vermiculite is a soft mineral and has the unique ability to exfoliate or expand up to 20 times its original size with the application of flash heat between 400 and 1,100 °C (Lockey, 1981; Meisinger, 1985; Moatamed et al., 1986). Exfoliation can also be achieved by chemical processes such as soaking in hydrogen peroxide, weak acids, and other electrolytes. Expanded vermiculite is lightweight, noncombustible, and chemically inert with a high surface area and ion-exchange capacity (Moatamed et al., 1986).

Crude vermiculite has a loose bulk density of 640 to 1000 kg/m^3, whereas exfoliated vermiculite expands to a bulk density of 56 to 192 kg/m^3. It also has a very low thermal conductivity and a relatively narrow range of cation-exchange capacity, primarily associated with magnesium.

2.2 PRODUCTION AND INDUSTRIAL USE

Vermiculite has been mined in the United States since 1929. The amount of vermiculite produced in the United States in 1988 was 275,000 metric tons (Potter, 1990). The largest domestic producer is W.R. Grace and Co., with mines in Libby, MT, and Enoree, SC. Exfoliated vermiculite is produced by W.R. Grace and Co. at 29 plants in 24 states (of a total of 43 plants in 29 states). Vermiculite is also mined and processed by Patterson Vermiculite Co. near Enoree, SC, and by Virginia Vermiculite, Ltd., in Louisa County, VA (Meisinger, 1985).

Vermiculite's capacity for reversible cation exchange permits its use as a fertilizer and soil additive, and its low thermal conductivity permits wide usage as a heat-resistant insulator (Dixon et al., 1985; JRB, 1982). Vermiculite is also used as an inert carrier for pesticides and herbicides and as an absorptive material in the water purification and chemical industries (Moatamed et al., 1986).

The largest portion of exfoliated vermiculite is used in construction aggregates (51%), followed by insulation (26%), agriculture (22%), and other end uses (1%). Vermiculite is sold in five grades (Dixon et al., 1985).

2.3 SOURCES OF EMISSIONS

Emissions of vermiculite are associated with mining, milling, and exfoliation processes; transportation; and its use in secondary productions. These emissions can also involve the release of asbestos or asbestiform fibers, which are readily transported through the atmosphere (Dixon et al., 1985). Estimates of the amounts of vermiculite released into the environment during mining, processing, transport, and use have been reported by JRB (1982, as cited in Dixon et al., 1985). Based on a production volume of 1 million tons (1.2×10^9 kg) of vermiculite ore mined and beneficiated in 1979 to produce 314×10^6 kg of crude vermiculite, approximately 802×10^3 kg were released into the air, $89{,}900 \times 10^3$ kg were released into water, and $2{,}490 \times 10^3$ kg were released as solid waste. The water releases were disposed of in settling ponds, and the water was recycled. Releases into air resulted from fugitive releases from dust-control equipment, whereas particulates collected in the dust control system constituted the solid wastes that were disposed of in landfills. For estimates of releases during exfoliation, JRB (1982, as cited in Dixon et al., 1985) assumed that dust-control equipment was 98% efficient. Releases during transport are negligible, whereas the largest release is during direct application of vermiculite, as a component of agricultural products such as fertilizers and soil conditioners, to soil.

2.4 EXPOSURE

Exposure to vermiculite occurs mainly via inhalation; ingestion and dermal absorption are insignificant routes of exposure. Wastewater from vermiculite mining, milling, and exfoliation is generally sent to settling ponds and the supernatant is recycled, thus no discharge of asbestos-laden vermiculite to the environment is expected. Because of this, ingestion via this route either as a potable water source or through entry into the food chain is not expected to be significant. Dermal contact would not be expected to result in exposure since the fibers would probably not penetrate intact skin surfaces. Exposure to asbestos- or asbestiform fiber-contaminated vermiculite occurs in the occupational environment or from ambient air near point sources and is consequently of concern.

Several studies have been conducted to determine occupational exposure to vermiculite. Lockey et al. (1984) assessed the respiratory status of workers exposed to tremolite-contaminated vermiculite in an Ohio processing company. A total of 512 employees participated in the study. Exposure estimates were divided into low, medium, and high exposure departments. The low exposure department consisted of the chemical process, research, and front office areas; the medium exposure department consisted of the central maintenance, packaging, and warehouse areas; and the high exposure department consisted of the expanding, maintenance, and plant areas. Due to tremolite contamination, optical fiber counts of tremolite were performed. Particles with a length greater than 5 μm, a diameter less than 3 μm, and an aspect ratio of 3:1 or greater were counted as fibers. Prior to 1973, exposures were generally higher. In Group I (low), the 8-h, TWA exposure was estimated at 0.049 fibers/cm^3. The Group 2 (medium) TWA exposure estimates ranged from 0.110 to 0.415 fibers/cm^3, whereas the Group 3 (high) TWA exposure estimates ranged from 1.264 to 1.511 fibers/cm^3. In 1974, improved environmental controls were implemented and the TWA exposure estimates decreased in Groups 2 and 3. Group 2 estimates ranged from 0.031

to 0.131 fibers/cm^3, whereas those for Group 3 ranged from 0.212 to 0.375 fibers/cm^3. The work areas with highest airborne fiber exposure were the vermiculite expander's area and the vermiculite railroad car and truck unloading areas.

Miners' exposure to vermiculite in a Montana mine was studied by McDonald et al. (1986). Concern for the health of the miners stemmed from the fact that the ore body is contaminated with fibrous amphibole deposits in the tremolite series. Tremolite exposures were measured by standard optical microscopy. Due to the short-term personal samples, the authors stated that the exposure estimates probably reflect ambient concentrations rather than TWA exposures. The highest dust concentrations (101.5 to 124.9 fibers/cm^3) occurred in the dry mill prior to 1970. The concentrations then dropped significantly (22.1 to 27.1 fibers/cm^3) after the installation of a major piece of ventilation equipment. For the period 1960 through 1970, exposure estimates in the mine pit, skip boot, river station, hauling, and testing areas were 2.3 to 12.5, 2.0 to 68.8, 4.7 to 12.0, 5.4 to 24.0, and 1.0 to 2.9 fibers/cm^3, respectively. For the period 1970 through 1980, exposures for all areas ranged from 0.2 to 1.5 fibers/cm^3.

Exposure to tremolite–actinolite–contaminated vermiculite at a mining and milling operation in Libby, MT, was studied by Amandus et al. (1987a). The site was divided into 25 location-operations, and sampling information from the period before 1950 through 1982 was collected and analyzed. Fibers counted were >5 μm in length and >0.45 μm in width. Prior to 1964 the greatest exposure came from dry mill jobs, and estimates for working areas, sweepers, skipping, and the quality control laboratory were 168, 182, 88, and 13 fibers/cm^3, respectively. From 1964 to 1977, exposure estimates decreased greatly. For the same operations, they were 33, 36, 17, and 3 fibers/cm^3, respectively. Prior to 1971, exposure estimates for mining jobs including drilling and nondrilling operations were 9 to 23 and <2 fibers/cm^3, respectively. At the river loading station, exposure estimates prior to 1971 for ore loading at the river office, the conveyor tunnel, the river dock, and the river station bin area ranged from 5 to 82, 10 to 11, 112 to 113, 5 to 117, and 20 to 21 fibers/cm^3, respectively. Exposure estimates for all operations decreased annually from 1972 to 1976 and leveled off in 1982. Exposures in most areas during 1977 through 1982 were <1.0 fibers/cm^3 and ranged from 0.6 to 1.0 fibers/cm^3 in the mill. Estimates for an 8-h TWA fiber exposure from 1981 through 1982 ranged from 0.6 to 0.8 fibers/cm^3 for mine and mill jobs. However, based on samples taken by the company in 1984, the average TWA exposure was 0.1 fibers/cm^3.

Due to the presence of asbestos as a contaminant in vermiculite, Dixon et al. (1985) conducted a study to determine airborne concentrations of asbestos in processing plants. Sampling was conducted in 1980 at the W.R. Grace mine and milling facility near Libby, MT, from October 21 through October 26, and at both the Grace and Patterson mine and processing facilities near Enoree, SC, from November 3 through November 6. Both air samples and bulk samples were collected at each location. The sampling methods employed attempted to capture particles during various stages of production. The possibility existed that during exfoliation asbestos fibers trapped between vermiculite plates could be released; therefore, samples were analyzed as they were received using an exfoliation process that allowed the samples to retain the asbestos to determine if additional fibers were shed. Laboratory analysis suggested that a higher quantity of asbestiform fibers existed in smaller-size grades of vermiculite than in larger-size grades. Multiple grades of bulk samples, which were mined from the Grace facility at Libby and observed under transmission electron microscopy (TEM), consisted of the amphibole group minerals anthophyllite and actinolite-tremolite and contained a range of 1 to 1,800 $\times$ 10^6 fibers/kg. Corresponding concentration ranges were from 1 to 41,000 ppm (Dixon et al., 1985). Exposure to asbestos was higher in miners and millers of vermiculite than in exfoliaters (Table 2-1).

The National Institute for Occupational Safety and Health has conducted two workplace exposure surveys. The National Occupational Hazard Survey (NOHS), conducted from 1972 to 1974, estimated the number of workers potentially exposed to chemical agents in the workplace in 1970 (NOHS, 1976). These estimates were derived from observations of the actual use of the agent, the use of trade name products known to contain the agent, and the use of generic products suspected of containing the agent. NOHS estimated that 104,456 people were potentially exposed to vermiculite: 4% were exposed to the actual product, 21% were exposed to trade name products, and 75% were exposed to generic products suspected of containing vermiculite.

The National Occupational Exposure Survey (NOES), conducted from 1980 to 1983, estimated the number of workers potentially exposed to chemical agents in the workplace in

TABLE 2-1. OCCUPATIONAL EXPOSURE TO AIRBORNE CONCENTRATIONS OF ASBESTOS IN VERMICULITE PROCESSING PLANTS

Population	Asbestos Fiber Concentration[a] (fibers/cm^3)	Comments
Miners and millers of vermiculite		
Grace mine and mill at Libby	0.03	Front loader, mine
	<0.01	Pit haul driver, mine
	1.7	Mine analyst, mine
	0.8	Bottom operator, mill
	6.4	No. 2 operator, mill
	0.11	Operator mine
	0.15	Shuttle truck between plants
Grace mine at Enoree	0.15	Truck driver
	<0.01	Dragline operator
Grace mine at Enoree	0.03	Mill monitor
	0.14	Mill lab technician
Exfoliators of vermiculite		
Grace facility at Enoree	0.08	Bagger (Grade 4)
	0.08	Bagger (Grade 3)
Patterson facility (beneficiation, exfoliation at Enoree)	0.02	Payload operator
	0.16	Plant foreman
	0.05	Bagger/forklift operator

[a]Concentrations are an average of values determined by two independent laboratories, Ontario Research Foundation and IIT Research Institute.

Source: Dixon et al. (1985).

1980 (NOES, 1984). Unlike NOHS, the NOES estimates were based only on observations by the surveyor of the actual use of the agent. The NOES estimated that 4,293 workers, including 365 females, were potentially exposed to vermiculite in the workplace in 1980.

Consumers can potentially be exposed to vermiculite due to its various uses; however, no data are available to estimate vermiculite levels. Table 2-2 lists the ranges of asbestos concentrations to which consumers may be exposed as a result of asbestos-contaminated vermiculite use.

TABLE 2-2. SUMMARY OF OCCUPATIONAL AND NONOCCUPATIONAL INHALATION EXPOSURE TO ASBESTOS IN VERMICULITE

Population	Number of Persons Exposed	Asbestos Exposure Level[a] fibers/cm^3	$\mu g/m^3$	Duration (hours)
Occupational				
Miners and millers	250	ND[b]-9.7	--	43.0
Exfoliators	1,694-1,979	ND-0.38	--	41.5
Users of exfoliated vermiculite	1,694-1,979	ND-0.38	--	41.5
Aggregates and insulation producers	298	--	6,800	36.9
Transporation				
Truck	129	<0.01-0.3	--	39.9
Rail	108	Unknown	--	39.9
Warehouse	Unknown	0	--	39.9
Consumers				
Attic insulators	188,000	--	6,800	8
Garden fertilizers	32,000,000	--	20	1
Lawn	74,400,000	--	4.4	4
Disposal		Unknown		
Food		Unknown		
Drinking water		Unknown		
Ambient air				
Near mills	4,600	ND-0.5	--	168
Near exfoliation plants	13,147,496	--	5.0×10^{-5} 2.5×10^{-2}	168
Ambient water		Unknown		
Ambient land		Unknown		

[a]Data expressed either by fiber count or by weight.
[b]ND = None detected.

Source: Dixon et al. (1985).

2.5 AMBIENT LEVELS

There was limited information on the ambient levels of vermiculite. Ambient levels of fibers (vermiculite contaminated with asbestos) in the vicinity of mines and mills were reported by MRI (1982, as cited in Dixon et al., 1985). A maximum of 0.5 fibers/cm^3 was recorded in Libby about 4.5 km downwind from the mine, 0.03 fibers/cm^3 was recorded at the W.R. Grace mine in Enoree, 0.05 fibers/cm^3 was reported 100 m downwind of the mill, and 0.02 fibers/cm^3 was reported within 50 m of the Patterson site in Enoree.

2.6 ENVIRONMENTAL FATE

Vermiculite is a naturally-occurring clay mineral, formed through weathering of primary aluminosilicate minerals such as biotite, feldspar, and hornblende. In the environment, it eventually decomposes into simpler clay minerals. In general, a clay crystal lattice is comprised of sheets of silica tetrahedra or alumina octahedra. This sheet structure results in negatively charged particles with extremely high surface areas (750-800 m^2/g for vermiculite) that have an affinity for water and cations.

Vermiculite's crystal unit is comprised of an octahedral layer sandwiched between two tetrahedral layers. Magnesium may substitute for some aluminum in the octahedral layers, aluminum replaces much of the silicon in the tetrahedral layers, and water molecules hold crystals together. When other water molecules are attracted to the spaces between crystals, the lattice expands somewhat. The magnesium-aluminum and aluminum-silicon substitutions also leave vermiculite with a very high net negative charge, so it has the highest cation exchange capacity (CEC) of any clay—about 150 milliequivalents (meq) per 100 g of material (other clays range from about 15 to 100 meq/100 g) (Brady, 1984). This high CEC gives vermiculite the ability to adsorb a variety of cations (including plant nutrients) and some organic compounds.

Thus, while vermiculite is not in itself highly reactive, its high surface area and sorptive capacity strongly influence the behavior of other materials in soil. The only important physicochemical factors influencing the transport of vermiculite are density and particle size and shape (Dixon et al., 1985). Because vermiculite occurs in nature in the smallest soil particle size fraction (less than 0.002 mm), it is very easily transported by wind and water.

Properties such as melting and boiling point, solubility, vapor pressure, and octanol/water partition coefficient do not significantly affect its transport.

2.7 ANALYTICAL METHODS

The analysis of samples of vermiculite is dependent upon the sampling technique, sample preparation, and the resolution capabilities of the instrumentation.

Current sampling techniques have been changed or modified from earlier methods due to limitations of these methods. In several studies, the early sampling method employed was the midget impinger method. Although an acceptable method at the time, the impinger technique tends to underestimate fiber exposure in tremolite-contaminated vermiculite. Later sampling was done by the membrane filter to give a more complete estimate of exposure (Amandus et al., 1987a; Dixon et al., 1985; McDonald et al., 1986). Lockey et al. (1984) also employed a modified version of the industrial breathing zone method that enables the sampler to estimate exposure by job area.

Airborne samples of vermiculite are usually analyzed first by polarized-light microscopy with dispersion staining to identify contaminants. A major limitation of this method is that only massive amphibole fragments can be seen (Lockey et al., 1984; Moatamed et al., 1986). Amandus et al. (1987a) and Dixon et al. (1985) subjected tremolite-contaminated vermiculite dust to phase-contrast light microscopy, which allowed sizing of the tremolite fibers according to length, width, and aspect ratio. After this initial analysis, airborne samples of vermiculite can be subjected to a variety of analytical methods depending upon the information sought. Scanning electron microscopy (SEM) using energy dispersive x-ray analysis and TEM using selected area electron diffraction allows elemental chemical analysis and an estimate of the abundance of vermiculite present in the sample (Lockey et al., 1984; McDonald et al., 1986; Moatamed et al., 1986). An analytical technique employed by Moatamed et al. (1986) subjected expanded and unexpanded forms of vermiculite to SEM for comparative identification of fibers as small as 0.01 μm in diameter. Wada and Kamitakahara (1991) investigated lattice dynamics of vermiculite by inelastic neutron scattering and Raman scattering.

Bulk analysis of vermiculite samples was performed by Amandus et al. (1987a) and Dixon et al. (1985). Amandus et al. (1987a) subjected bulk samples of vermiculite to polarized-light microscopy to locate fibrous material and to determine physical characteristics. Further analysis by scanning transmission electron microscopy with an energy dispersive x-ray spectrometer determined the fibrous mineral content for classification. Dixon et al. (1985) analyzed bulk samples of vermiculite by electron microscopy to determine fibrous mineral content. Optical microscopy and x-ray diffraction techniques were then employed to determine fiber classification. The additional step of subjecting exfoliated vermiculite to TEM allowed the authors to determine if any fibers were "trapped" in exfoliated vermiculite.

3. TOXICOLOGY

3.1 RETENTION, BIODISPOSITION, AND CLEARANCE

There was no information in the available literature on the retention, biodisposition, or clearance of vermiculite. In general, inhaled particles may enter the body either by inhalation or by ingestion. Most ingested particles apparently pass through the gastrointestinal tract without being absorbed.

A number of mechanisms influence the deposition of both nonfibrous and fibrous particles in the respiratory tract. For example, deposition in the nasal passages occurs mainly by inertial impaction due to the high velocity of the air stream. Impaction is also an important factor in the larger conducting airways but, as the flow rate diminishes and the airway caliber reduces, gravitational settling assumes greater significance. The development of secondary flows at airway bifurcations enhances the deposition of both nonfibrous (Schlesinger et al., 1977) and fibrous particles (Morgan et al., 1977; Brody et al., 1982) at these sites. For particles that are small enough to reach the alveolar region of the lung, diffusion becomes an important factor in determining deposition. With fibrous particles, other mechanisms such as interception and electrostatic attraction assume importance.

When nonfibrous compact particles are inhaled, most of those having a diameter greater than about 5 μm are trapped in the nasal passages (Walton, 1982, as cited in National Research Council, 1984); however, the aerodynamic behavior of fibers differs from that of nonfibrous particles. Fibers with a given diameter will behave aerodynamically in a similar manner to spherical particles with a significantly larger diameter (Gross, 1981; Timbrell et al., 1970). The equivalent aerodynamic diameter of a particle (D_{ae}) is defined as "the diameter of a unit-density sphere with the same falling speed as the particle".

Particles and fibers deposited in the nasal passages and in the conducting airways of the lung are rapidly cleared by mucociliary action, but the fate of those deposited in the alveolar region depends primarily upon their solubility and length. For insoluble particles or fibers, such as amphibole asbestos and possibly vermiculite, clearance depends upon their transport to the ciliated airways for all practical purposes. It appears that this process is mediated by alveolar macrophages and that clearance decreases with increasing fiber length. (Timbrell, 1982). Indeed, it appears that fibers with length exceeding a critical value (about 15 μm) cannot be mobilized by macrophages and remain in the lung indefinitely unless removed by other mechanisms such as coughing. Short fibers may also be transported within macrophages to the regional lymph nodes. Epithelial cells are also reported to take up asbestos fibers (Pinkerton et al., 1983), and fibers may be translocated between epithelial cells to the interstitium and pleura (National Research Council, 1984).

Studies of miners and millers exposed to vermiculite contaminated with tremolite suggest that vermiculite may be inhaled, deposited, and retained by the lungs (Amandus et al., 1987b; Lockey et al., 1984). In one study, the estimated cumulative exposure to contaminated vermiculite fibers (particles with a length >5 μm and a diameter <3 μm, and an aspect ratio $\geq 3:1$) of a group of 512 workers (480 males, 32 females) was 0.01 to 39 fibers/cm^3/year (Lockey et al., 1984). Pleuritic chest pain occurred in 4.4% (22) of the exposed population and was correlated ($0.05 > p < 0.01$) with cumulative fiber concentration. The authors suggested that these effects, which were not considered severe, were indicative of a low cumulative fiber exposure. A series of similar studies by Amandus and coworkers (1987a,b) support Lockey's findings.

3.2 ANIMAL TOXICITY

No information on the acute, subchronic, or chronic toxicity of vermiculite was found in the available literature. Similarly, there was no information on developmental or reproductive effects, genotoxicity, or in vitro cytotoxicity of vermiculite.

Results from one study indicate that vermiculite is not carcinogenic following intrapleural administration. Hunter and Thomson (1973) tested the carcinogenicity of vermiculite after intrapleural injection of 25 mg in 0.2 cm^3 saline into a group of 21-day-old female Sprague-Dawley rats. The vermiculite sample consisted of amorphous particles and had a particle size 93% <5 μm and 37% <2 μm. The animals receiving vermiculite developed granulomas in the lung and viscera, but no tumors developed after 104 weeks. A comparable dose of chrysotile asbestos produced mesotheliomas in 48% of the rats.

3.3 EFFECTS ON HUMANS

This chapter presents a critical review and analysis of the carcinogenic and noncarcinogenic effects in humans following exposure to vermiculite. Cross-sectional studies, clinical evaluations, and case reports are discussed, followed by reviews of retrospective and historical prospective studies.

3.3.1 Cross-Sectional Studies, Clinical Evaluations, and Case Reports

Results of three studies indicated an association between past fiber exposure and parenchymal and pleural radiographic abnormalities but no correlation with pulmonary function tests. The effect of smoking and the presence of tremolite−actinolite fibers confounded the findings of increased pleural disease.

In a review of nonasbestos fibrous materials, Lockey (1981) concluded that vermiculite itself did not produce adverse health effects, but noted that vermiculite ore may contain asbestos fibers. In a later study by Lockey et al. (1984), workers exposed to vermiculite contaminated with fibrous tremolite were examined. A total of 530 employees in a plant processing vermiculite ore to its expanded form were studied. Industrial hygiene sampling of airborne fibers was initiated in 1972, 15 years after the plant had begun using vermiculite. Particles with a length >5 μm, a diameter <3 μm, and an aspect ratio of 3:1 or greater were counted as fibers. A high-exposure group was identified and compared with the chemical processing facility where exposure was low. The highest cumulative fiber exposure for an employee was 39 fibers/cm^3-year; only 9.6% had an exposure greater than 10 fibers/cm^3-year, and 10.7% had been employed 20 years or more since initial exposure. A cluster of 12 cases of pleural effusions was identified in the high-exposure group of 194 workers. Radiographic changes correlated with exposure when age-matched groups and groups with comparable smoking habits were compared. The prevalence of pleuritic changes was significantly related to fiber exposure, but no correlation was found between fiber exposure and various pulmonary function tests.

McDonald et al. (1986) obtained chest radiographs from three groups of workers from a vermiculite mine in Montana. The first group consisted of 164 men and women employed by the company on July 1, 1983. The second group consisted of 80 men who had been hired before January 1, 1963, and had been employed for at least one year. The third group comprised 47 men without known exposure to dust who were not selected or matched with the mine workers but were used only to control the reading process. A logistic regression analysis showed that there was an effect of cumulative exposure, age, and smoking on the prevalence of small opacities ($p \leq 0.02$). Pleural thickening on the chest wall was affected by age and cumulative exposure ($p \leq 0.02$) but not by smoking. There were several potential problems in this study. First, exposure estimates were approximate, particularly for those employed before 1972. Second, the radiographic techniques and radiographic readings were major sources of variation. Third, the sample size was small. At present exposure levels, which were reported to average 0.1 fibers/cm^3, no excess of radiological change was detected after a working life of 40 years. The authors suggested that by retirement age, the increase in prevalence of small parenchymal opacities ($\geq$1/10) was between 5 and 10% per 100 fibers/cm^3•years.

Amandus et al. (1987b) conducted a cross-sectional morbidity study of 191 men employed for at least five years between 1975 and 1982 at a vermiculite ore mine and mill near Libby, MT. Radiographic examinations had been administered by a local hospital to all active workers in 1959 and annually since 1964. Questionnaires on smoking habits and respiratory symptoms had been administered by the company to most active workers employed after 1975. Chest radiographs were available for 184 workers, and questionnaires about smoking and respiratory symptoms were available for 121 workers. Radiographic findings were independently interpreted by three readers blinded to other data. The radiographic readings indicated that the prevalence of small opacities was 10%, any pleural change was 15%, pleural calcification was 4%, and pleural thickening on the wall was 13%. Fiber exposure, as measured by fiber-years, was significantly related to small opacities, any pleural change, and pleural thickening on the wall ($p < 0.05$). The prevalence of small opacities was related to age and fiber-years but not significantly related to smoking. The confounding effect of smoking could not be accurately assessed, however, due to the small number of nonsmokers (25 overall).

Hessel and Sluis-Cremer (1989) studied 172 workers mining and processing South African vermiculite, which appears to contain some asbestos but at a low level by comparison with that in Libby, MT. The cohort of all black workers underwent x-ray examination and lung function testing and completed a respiratory symptom questionnaire. The vermiculite workers were compared with other workers involved in the mining or refining of copper. Only two of the vermiculite workers showed evidence of small opacities of 1/0 or more (according to the ILO 1980 classification), lung function was comparable with the other groups of workers, and there was no excess of respiratory symptoms among the vermiculite workers. The authors concluded that workers exposed to vermiculite that is minimally contaminated with asbestos are probably not at risk for pneumoconiosis, lung function impairment, or respiratory symptoms. The study suffers from limitations: (1) Dust exposure data are very sketchy, (2) a mortality study would be impractical due to the limited death registration for rural blacks, and (3) the sample size was small enough that only large effects of vermiculite exposure would have been detected. As such, the findings from this study cannot exclude the risk of mesothelioma caused by amphibole contamination of the vermiculite.

3.3.2 Retrospective, Prospective, and Historical Prospective Studies

Amandus and Wheeler (1987) conducted a historical prospective mortality study of 575 men hired prior to 1970 and employed at least one year at the vermiculite ore mine and mill near Libby, MT. Vital status was ascertained for 569 of the 575 cohort members (99%) as of December 31, 1981. Death certificates were obtained for all but two of the decedents (1.2%) and coded according to the 8th Revision of the ICD. Expected deaths were calculated from the U.S. white male death rates. Individual cumulative fiber exposure estimates (fiber-years) for the cohort were computed for 25 "location-operations" (LOs) for the years after 1968 by using an arithmetic average of fiber concentrations (fibers per centimeter cubed) and for the years before 1968 by using an arithmetic mean of dust concentrations (mppcf). Vermiculite ore was found to be contaminated with fibrous tremolite−actinolite (Amandus et al., 1987a).

The results of the mortality analysis indicated a significantly increased risk of mortality for lung cancer (20 observed, 9.0 expected, standardized mortality ratio (SMR) = 223.2, $p < 0.01$) and NMRD (20 observed, 8.2 expected, SMR = 243.0, $p < 0.05$). An analysis by exposure, measured as fiber-years (f-y), showed a significant increase in mortality in the highest exposure category (>399 f-y) for both lung cancer (10 observed, 1.7 expected, SMR = 575.5, $p < 0.01$) and NMRD (7 observed, 1.8 expected; SMR = 400.7, $p < 0.01$).

Mortality from NMRD was also significantly elevated in the lowest exposure category (<150 f-y) (8 observed, 3.6 expected, SMR = 220.0, $p < 0.05$). Mortality from lung cancer and NMRD was further evaluated by f-y and years of latency. No clear pattern emerged with respect to latency for lung cancer, although the significant increases occurred in the highest f-y exposure category (>399) at <10 years latency (2 observed, 0.2 expected, SMR = 1,370.2, $p < 0.05$) and ≥20 years latency (7 observed, 1.0 expected, SMR = 671.3, $p < 0.01$). No exposure-response association was found for NMRD; significant effects occurred after 10 to 19 years of latency for 100 to 399 f-y (3 observed, 0.6 expected, SMR = 459.9, $p < 0.05$) and >399 f-y (4 observed, 0.5 expected, SMR = 774.5, $p < 0.01$). At ≥20 years, only the lowest exposure category (<50 f-y) was significant (7 observed, 2.1 expected, SMR = 327.8, $p < 0.05$). There was insufficient power to detect significant increases in risk at other exposure and latency periods. In addition to small cohort size and insufficient power to detect lung cancer and NMRD among the whole cohort, a confounding variable in this study was the effect of smoking. The proportion of current and former smokers among 161 vermiculite workers was found to be 15.5% higher than that among U.S. white males in 1975.

McDonald et al. (1986) conducted an independent historical prospective mortality study of the same vermiculite ore mine and mill studied by Amandus and Wheeler (1987) and obtained similar results. The cohort consisted of 406 men hired prior to 1963 who were employed for at least one year. Compared to the cohort studied by Amandus and Wheeler (1987), this study had a smaller cohort (406 vs. 575 men), whose members were hired earlier (1963 vs. 1970), and a longer followup (July 1, 1983 vs. December 31, 1981). In both studies, cohort members were employed at least one year and death certificates were coded by the same nosologist. In addition to U.S. white male death rates, McDonald et al. (1986) used Montana males as a further comparison for deaths from respiratory cancer. By the end of the followup period, July 1, 1983, 226 (55.7%) of the 406 workers were alive; 165 (40.6%) had died; and 15 (3.7%) were lost to followup. Death certificates were obtained for all but two (98.7%) of the decedents. Prior to 1965, investigators assumed mean dust concentrations of 101.5 fibers/cm^3. Between 1970 and 1974, mean dust concentrations measured through personal and area sampling were found to be 22.1 fibers/cm^3. The current mean dust concentration is 0.1 fibers/cm^3.

Compared to U.S. white males, the cohort experienced excess mortality from all causes (165 observed, 141.0 expected, SMR = 117, p <0.05), respiratory cancer (23 observed, 9.39 expected, SMR = 245, p <0.001), NMRD (21 observed, 8.24 expected, SMR = 255, p <0.001), and accidents (SMR = 214, p <0.005). Compared to Montana males, who had lower expected deaths from respiratory cancer than U.S. white males, the SMR for respiratory cancer was slightly higher (303). Four deaths were from malignant mesothelioma.

In addition, McDonald et al. (1986) conducted a nested case-control analysis of exposure-response of 23 respiratory cancer deaths. Controls for each respiratory cancer case were selected from men who survived beyond the age of death of the case and who worked within three years of the case. For each control, exposure accrued until the age of death of the matching case. This nested case-control analysis resulted in a statistically significant linear relationship between relative risk for respiratory cancer and cumulative exposure, and was most pronounced 20 or more years after first employment (chi square = 7.04, p <0.01).

The investigators concluded that the cohort was small but was sufficient to show that workers in the mining facility experienced a serous hazard from lung cancer, pneumoconiosis, and mesotheliomas. They attributed those diseases to tremolite contamination of vermiculite ore and the dusty conditions prior to 1974. As in the study of Amandus and Wheeler (1987), the presence of tremolite prevents any conclusions as to the role of vermiculite in causing lung cancer.

McDonald et al. (1988) studied a small cohort of 194 men with low exposure to fibrous tremolite (mean 0.75 f/ml•y) in the mining and milling of vermiculite in the Enoree region of South Carolina. The cohort experienced 51 deaths, 15 years or more from first employment. The SMR (all causes) was 117, reflecting excess deaths from circulatory disease. There were four deaths from lung cancer and 3.31 expected (SMR 121, 95% CI 0.33 to 3.09). Three of the four deaths were in the lowest exposure category (<1 f/ml•y); no deaths were attributed to mesothelioma or pneumoconiosis. A radiographic survey of 86 current and recent South Carolina employees found four with small parenchymal opacities (≥ 1/0) and seven with pleural thickening. These proportions were not higher than in a nonexposed group.

Examination of sputum from 76 current employees showed that only two specimens contained typical ferruginous bodies, confirming low cumulative fiber exposure.

The American Thoracic Society (ATS, Weill et al., 1990) discusses the health effects of tremolite and reviews the studies of vermiculite health effects. The ATS notes that the South Carolina study does not add information because a detectible increase in lung cancer risk would not have been expected because of the low exposure levels and the small size of the cohort. They additionally state that the observation for the Montana cohort of a dose-response relationship for lung cancer risk is important evidence of tremolite asbestos as a carcinogen in vermiculite mining, but note that, because this is based on only one cohort and because no other data on other relatively large populations of vermiculite miners are available, appropriate caution in interpreting nonreplicated epidemiological study results is warranted.

In regards to tremolite asbestos, the ATS (Weill et al., 1990) concludes the following after a review of other tremolite studies beyond those of contaminated vermiculite.

1. Unquestioned health effects of tremolite asbestos have been demonstrated in both humans and animals. These effects are identical to those produced by other forms of asbestos.
2. There may be important physicochemical distinctions between asbestosform and non-asbestosform tremolite dust particles. However, there appears to be considerable controversy in applying these mineralogic definitions to specific samples of minerals, particularly individual particles viewed microscopically after collection by air sampling or found in human lungs or when used experimentally.
3. At present, the prudent public health policy course is to regard appropriately sized tremolite "fibers", in sufficient exposure dose (concentration and duration), as capable of producing the recognized asbestos-related diseases, and they should be regulated accordingly.

In summary, after examining the above studies and reviews, the weight of evidence for a causal relationship between exposure to vermiculite and lung cancer or NMRD is inadequate because vermiculite ore was found to be contaminated with asbestos. However, there is sufficient evidence for asbestos-contaminated vermiculite.

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