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Mary S. Wolfe, Ph. D.
NIEHS Mail Drop A3-07
111 TW Alexander Drive
Room A-329
Building 101 South Campus
Research Triangle Park, NC 27709

November 29, 2000

Re: 10th ROC Nominations: Solicitation of Public Comment
"Talc Containing Asbestiform Fibers"

Dear Dr. Wolfe:

In response to the captioned call for public comment, I have enclosed written comments in support of the oral presentation requested on November 10, 2000. It is intended that this submission be considered by the NTP Board of Scientific Counselors' Subcommittee prior to the scheduled meeting of the subcommittee on December 13, 14 and 15, 2000.

Please confirm a time and date regarding the oral presentation as soon as you are able.

Very truly yours,

R. T. VANDERBILT COMPANY, INC.

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THE NATIONAL TOXICOLOGY PROGRAM
BOARD OF SCIENTIFIC COUNSELORS' MEETING
December 13-15, 2000

Review of Nominations for Listing in the 10 Report of Carcinogens

SUPPORT DOCUMENT: ORAL PRESENTATION

NOMINATION:

TALC CONTAINING ASBESTIFORM FIBERS

Prepared By:

John W. Kelse
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Manager, Corporate Risk Management Dept.

R. T. VANDERBILT COMPANY, INC.
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November 28, 2000

SUPPORT DOCUMENT: ORAL PRESENTATION

December 13-15, 2000

NOMINATION: Talc Containing Asbestiform Fibers

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The nomination of "talc containing asbestiform fibers" is based almost entirely on Vanderbilt talc. Arguably, the nomination might simply read " Vanderbilt talc".

Fortunately, Vanderbilt talc is one of the most studied talcs in the world from both a mineralogical and biological perspective. As a result, it was relatively easy to review the NTP background document for accuracy, balance and completeness.

On June 2, 2000, extensive reference materials with cover comments were submitted to the NTP in response to its request for comments. A copy of that submission, with a listing of reference materials provided, is appended to this submission (see **Tab A**). The previously submitted document is being resubmitted because it appears to have been overlooked by the review groups.

Had this earlier submission been considered, many lapses noted in the NTP background document might have been avoided. This submission addresses several of the most important lapses noted in the draft NTP review.

1. The mineral makeup of Vanderbilt talc is not clearly or correctly stated.

The mineral makeup by weight % of Vanderbilt talc appears below. The mineral blend varies somewhat depending upon the grade, but the ranges are inclusive of all grades.

Talc: **20-40 %**
(of this, Talc & Talc/amphibole mixed or transitional fiber = 0.5 to 5.6 %) *
Tremolite (nonasbesiform): **40-60 %**
Serpentine (antigorite-lizardite): **15-30 %**
Anthophyllite (nonasbestiform): **1-10 %**
Quartz: **< 1% when detected at all**

*** Of this combined fiber, approx. <0.05 to 1.8 % (by weight – whole product) is asbestiform (average all grades <0.50 %) – this <u>is not</u> asbestos**

Note that all the amphibole & serpentine content is "nonasbestiform", which means there is no asbestos in this talc. The minor amount of talc fiber that would be classed as asbestiform is not defined by mineral scientists, or any regulatory standard, as asbestos.

Vanderbilt's original NTP submission contained a number of analytical documents in support of the above table. Additional documents are appended to this submission which further confirm the above composition. Pertinent definitions and photomicrographs are appended as well (**Tab B** - OSHA Salt Lake City Report to the CPSC, RJLee Inc. Report on talc fiber content, definitions & photomicrograph examples & OSHA Asbestos Std.).

2. Because asbestos is incorrectly linked to this talc, health studies of Vanderbilt talc workers suffer from an asbestos "expectation bias". This bias is reflected in the NTP background document as well.

The composition of Vanderbilt talc is extremely complex, and the source of considerable analytical confusion and incorrect literature citations over the years. References behind Tab B provide detail in regard to its complexity and common sources of analytical error.

In its original 1980 health study, for example, NIOSH flatly stated that Vanderbilt talc contained **"40 – 60 % tremolite and anthophyllite asbestos"** (ref. 1). If true, this would be a particularly potent asbestos exposure, since most asbestos mines only contain a few percent asbestos in their ore – typically 3 to 10% in the raw ore (Ref. 2,3). The price per ton of asbestos is often many times that of talc (Ref. 4). One must wonder why Vanderbilt would be mining industrial talc in a deposit so rich in "asbestos", if NIOSH was correct.

With this major (though incorrect) asbestos exposure in mind, NIOSH then found a moderate excess in lung cancer in the Vanderbilt talc cohort and concluded that **"exposures to asbestiform tremolite and anthophyllite stand out as the prime suspected etiologic factors associated with the observed increase in bronchogenic cancer."** The "asbestos" referenced was actually nonasbestiform amphibole cleavage fragments, later determined not to pose a carcinogenic risk (Tab. B - OSHA).

The excess lung cancer, however, was only seen among the miners – not among the more numerous millers, even though the millers had about the same or higher dust level exposures (see also discussion under section # 3 below).

NIOSH also studied Vermont talc workers and noted that these workers were not exposed to the "asbestos" present in Vanderbilt talc (ref. 5). Curiously, however, NIOSH recorded a similar excess in lung cancer among the Vermont miners but not among the millers as was seen among Vanderbilt talc miners and millers with > one year exposure.

Vermont (> 1 Yr. Exp.)	**Miners: 5/1.15**	**435 SMR**	**Millers: 2/1.96**	**102 SMR**
New York (> 1 Yr. Exp.)	**Miners: 4/1.1**	**368 SMR**	**Millers: 1/1.4**	**71 SMR**

NIOSH concluded in the Vermont study that the source of the excess cancer among the miners came **" from some unknown etiologic agent".** This conclusion was reached because the dust exposure was higher in the mill – so there was no dust linked dose-response demonstrated. The same could be said regarding the Vanderbilt talc workers – but it wasn't.

The numbers of miner cases in both cohorts was very low, making this comparison somewhat tenuous (Lamm 4 cases; Selevan 5 cases). More importantly, however, the way in which both studies were considered by NIOSH as well as the NTP suggests that a dose-response relationship, when asbestos is not present, is important in determining causality. When asbestos is present (or thought to be present), however, dose-response relationships can be ignored. A more detailed discussion of this comparison may be found behind **Tab C** (Lamm, et al).

Several tables in the NTP draft background document project a similar bias and further confuse this nomination. In these references, selected asbestos studies and health risks are cited when the talc exposure in question actually does not contain asbestos (i.e. Tables 4-6, pages 51 to 55, Tables 5-3 and 5-2). Moreover, if asbestos did exist in this talc, there would be no need for the nomination since asbestos is already listed by the NTP as a known human carcinogen, and is regulated as a carcinogen.

Interestingly, the NTP document justifies these references because asbestos is described as a "toxicological surrogate for asbestiform talc". There can be no mistaken a "same as" presumption (i.e. that any non-asbestos asbestiform fiber in talc is the "same as" asbestos biologically). This conclusion must be reasonably demonstrated – it cannot be presumed.

Further, the NTP draft document is incorrect in regard to how regulatory agencies and groups treat this nomination (p.15 and linked tables). The Environmental Protection Agency, the Mine Safety and Health Administration, the American Conference of Governmental Industrial Hygienists and the Occupational Safety and Health Administration only regulate asbestos. References to talc containing asbestos is correctly expressed by those groups as "talc containing asbestos", not "talc containing asbestiform fibers".

This is an extremely important distinction because it makes clear the intent of these standards. In contrast, the intent of this NTP nomination is very unclear. The importance of proper nomenclature was noted in Vanderbilt's earlier NTP submission and copies of the applicable regulatory citations appended. I have resubmitted these citations behind **Tab D.**

The NTP background document likely suffers in mineralogical clarity because the references it relies upon (the 1987 IARC monograph on talc and NIOSH mineralogy in particular) suffers from mineralogical clarity as well. These references address asbestos but then create ambiguity by using the phrase "asbestiform" instead of asbestos. Confusion is understandable but when these errors have been pointed out (and they have repeatedly been pointed out), they should not be perpetuated. A good rule of thumb might be – when you talk about asbestos, simply say asbestos and remember that the term "asbestiform" is not a synonym for asbestos. Contrary to statements in the NTP draft review, the words "asbestos" and "asbestiform" as well as other mineralogical terms, do have specific meanings. When the interpretation of health effects is based on an incorrect

understanding of the mineralogy, the health effects are also likely to be misinterpreted, and inappropriate animal studies reviewed (as they were in the NTP document).

3. Mortality studies of Vanderbilt talc miners and millers were not given a complete or balanced review.

In any effort to determine carcinogenic risk to humans, all available human studies would seem extremely relevant. While there are often no human data available, in the case of Vanderbilt talc there are six mortality studies (including a 1990 NIOSH update). Beginning with the earliest, these studies are listed below. A copy of each study was provided in the original submission.

	Pub. Year	Lung Cancer SMR	Cohort Size
NIOSH Publ. # 80-115	**1980**	**270**	**398**
Stille, W. Tabershaw	**1982**	**157**	**708**
Lamm S., et al.	**1988**	**220**	**705**
NIOSH HHE update	**1990**	**207**	**710**
Gamble J.	**1993**	**case/control**	**710**
Delzell E., et al.	**1995**	**254**	**818**

Earlier studies of New York State talc miners and millers referenced in the NTP draft background document (Kleinfeld, et al) are not specific to Vanderbilt talc. This is important, because since 1974 the only talc available as a product from upstate New York is Vanderbilt talc. Dust exposures from other area talc mines are likely to be similar in composition to Vanderbilt talc but are unlikely to be exactly the same, given the complex and highly varied geology of this mining region (ref. 6). In some cases areas mined decades ago are the same or similar to areas mined today, but in other cases they are not.

On a quantitative basis, early dust levels in area mines (as reported by Kleinfeld) show dust levels many times greater than those ever encountered at the Vanderbilt mine and mill. However, regardless of the qualitative and quantitative differences in exposure, the early Kleinfeld work addresses exposures that no longer exist.

These early studies suffer as well from a small cohort (260) and the absence of smoking data. Several subsequent mortality studies of Vanderbilt talc workers suffer from the same small numbers, as well as the absence of smoking information (the original NIOSH work among them).

The following table reflects lung cancer mortality and dust exposure data from the most up-to-date retrospective mortality study (Delzell, et al Ref. 7), and smoking data from the nested case control study (Gamble Ref. 8). Complete copies of both studies have previously been submitted to the NTP.

LUNG CANCER CASES

Delzell, et al: 1995: Cohort 818 SMR: 254

Covers all talc workers 1948 to the end of 1989 who worked for any period of time

Tenure Time at GTC	Work Area	Year DOD	Smoker*	Cigarette/Per Day
1 day	**MINER**	80	yes	20
4 days	mill	87	?	-
7 days	no exposure	86	?	-
7 days	no exposure	70	yes	20
18 days	mill	70	yes	40
18 days	**MINER**	88	?	-
1¾ months	**MINER**	70	yes	40
1¾ months	mill	88	?	-
2 months	**MINER**	71	yes	20
2 months	**MINER**	84	yes	40
2½ months	**MINER**	75	yes	20
2½ months	mill	84	yes	40
4½ months	**MINER**	81	yes	20
6 months	mill	89	?	-
7 months	no or min. exposure	85	?	-
10 months	**MINER**	73	yes	20
10½ months	**MINER**	85	?	-
2.1 years	**MINER**	82	yes	20
2.5 years	**MINER**	74	yes	20
2.6 years	**MINER**	61	yes	20
2.9 years	**MINER**	64	yes	10
3.6 years	**MINER**	89	?	-
9.9 years	min. exposure	86	?	-
12 years	**MINER**	75	yes	30
17 years	mill	76	yes	20
17 years	**MINER**	73	yes	20
17 years	**MINER**	84	yes	50
17 years	**MINER**	85	yes	20
23 years	mill	82	yes	20
23 years	**MINER**	79	yes	40
23 years	no exposure	88	?	-

*Smoking data obtained to 1985 (Gamble-Case Control). To that date, all cases smoked, 73% of controls smoked (includes a small proportion in both groups of ex-smokers).

Dust Exposures

	Cases	Resp. Mg/m^3 Dust Avg.	Mppcf Avg.	Fibers/cc
Mill:	7	0.46	14	1.5 - 8.0
Mine:	19	0.73	11	1.7 - 9.8
		(1970-85)	(1954-75)	

Tenure
<6 months: 14 (45%)
<1 year: 17 (55%)
<5 years: 22 (71%)

FOR CASES: Median cumulative respirable dust exposure for cases was 31% lower than overall cohort. RR = 0.66 Inverse Relationship

Mppcf Averages for Select Activities

Mill: Packers 16; wheeler mill operator 10, dryer 8

Mine: Crusher 17; slusher 15, trammer 7

Lung cancer case characteristics reflected in this table are consistent with those seen in prior studies. A simple review of this table is suggestive of whether exposure to Vanderbilt talc is or is not likely the cause of the lung cancer deaths observed (whatever the mineral composition of this talc).

Dust exposure assessments over the years show overall dust levels (total dust, respirable dust and basic fiber data) to be about the same in the mine and the mill. Some dust data suggest slightly higher levels in the mill for some activities (higher levels in earlier years as well) and slightly higher levels in the mine for certain mine activities (see Delzell and NIOSH dust data previously submitted). However, despite a relatively equal overall dust exposure and a slightly higher number of employees in the mill (336 millers versus 278 miners), the lung cancer cases are heavily concentrated in the mine (ref. 7 - Delzell). Five of the 31 lung cancer deaths had minimal dust exposure (typically clerical, office jobs). These general dust exposure/lung cancer case observations are not supportive of a dust etiology.

Most significantly, the Delzell study shows a direct inverse relationship for lung cancer cases and dust exposure. In this study, cumulative respirable dust exposure for cases was approximately 30% below the exposure for the overall cohort. The NTP draft review document recognized the importance of a dust exposure assessment. However, this study (peer reviewed and currently being prepared for publication), was provided in our original submission, but was not addressed by the NTP. This inverse dose-response relationship (RR = 0.66) certainly does not support a dust etiology.

Under the tenure column we see that over half the cases (55%) worked less than one year. There is exposure for a day, a week and so forth. A full 71% of the cases worked less than 5 years. If the dust were such a potent carcinogen (causing lung cancer after such a brief encounter), one would expect it to shine through even more dramatically among those with longer exposures. Possible explanations for the inverse effect have been offered (i.e. dirtier jobs for short term workers, etc.) However, these explanations are not supported in the dust exposure assessment nor in the case control study. Accordingly, an analysis by tenure does not support a dust etiology either.

In regard to smoking (at least for the cases and controls up to 1985, recorded in the case control study – Gamble Ref. 8), we see that all the lung cancer cases and 73% of the controls had been smokers (includes a few ex-smokers in each category). NIOSH argues that smoking would not account for all the excess. Gamble, however, argues that it is the more probable explanation, pointing out that the confidence interval of the 1990 NIOSH update cohort study would accommodate a smoking etiology. Gamble further points out that the latency from time of hire to time of death versus time of first smoking to death fits a smoking etiology better than a dust etiology.

The first and smallest NIOSH retrospective cohort study does not adequately address these key cause and effect questions. However, the NTP draft document clearly treats the early NIOSH work as pivotal with regard to this nomination, while completely ignoring the later NIOSH updated study which has an analysis by both latency and tenure and

nearly twice the number of cases (Ref. 9) NTP further compounds this error by understating and ignoring the more recent work of Gamble and Delzell et al which fulfills the requisites expressed by the NTP for control of confounding (smoking, other expsoures) and exposure-response analysis. The objectivity and validity of the NTP review of the talc's carcinogenicity cannot be given serious consideration when two of the most important studies of Vanderbilt talc workers are not even referenced or discussed (Brown, et al 1990; Delzell, et al 1995). Further, several thoughtful critiques of the NIOSH work (which were provided in earlier submissions), were not addressed.

The NTP defined the "known to be a human carcinogen classification" in it's 9th ROC as a category "reserved for those substances for which there is sufficient evidence of carcinogencity from studies **in humans** that indicates a **cause and effect relationship** between the exposure and human cancer" (emphasis added). I do not believe the epidemiology data available today reasonably indicates or supports such a relationship in regard to Vanderbilt talc (the obvious focal point of this nomination).

4 Animal data directly linked to Vanderbilt talc were overlooked and an important fiber cell study of Vanderbilt talc fiber was not fully addressed.

Two published animal studies that directly test Vanderbilt talc against asbestos were not addressed in the NTP background document. The following tables summarize the results of these studies. The complete studies may be found behind **Tab E** and have previously been submitted.

NCI ANIMAL STUDY
M. Stanton – Correlation of Fiber Dimension to Carcinogenicity

Material	Critical Dimension (log fibers/ug) < 0.25 um & > 8 um	Animals % tumors
Amosite	3.5	93 %
Tremolite Asbestos	3.1	100 %
Platy Talc	0	3 %
Vanderbilt Talc	3.3	0 %

Study involved pleurae implant in rats for periods of one year or more. 72 samples were used in the study. 7 talc samples were used, two of which were Vanderbilt talc (off the shelf).

BIOLOGIC TESTS OF TREMOLITE IN HAMSTERS
William Smith

Material	Tumors/Survivors After 350	500	600 Days
Tremolite Asbestos (sample 72)	3/20	5/6	5/1
Vanderbilt Talc (sample FD-14)	0/35	0/27	0/20

Study involved intrapleural injection in hamsters. 25 mg Dose

These pleural implantation and injection studies show a marked difference in tumor response between exposure to Vanderbilt talc and exposure to asbestos. These results do not support a "same as" risk.

No mesothelioma cases have been causally linked to exposure to Vanderbilt talc, even though two cases are recorded (latency too short in one case, very brief if any talc exposure followed by likely extensive exposure to asbestos in the other). These animal pleural studies do not support a biologically plausible association between Vanderbilt talc and mesothelioma. It should also be noted that the fibers measured and recorded in Stanton's Vanderbilt talc sample showed a concentration that fit his "critical dimension" range that should have resulted in upwards of 60% tumors. None, however, were observed. The only fibrous component capable of achieving this "critical dimension" in Vanderbilt talc (< 0.25 micrometers in width - longer than 8 micrometers) would be talc and transitional fiber (see fiber size documentation in prior submission). Again, it is presumed that these are the "fibers" being addressed in this NTP nomination.

In order to focus more directly on the minor but observable talc fiber content in Vanderbilt talc, a cell study was undertaken to test the cytotoxic and proliferative effects of fibrous talc and asbestos on rodent tracheal epithelial and pleural mesothelial cells. A copy of the complete study may be found behind **Tab F**. The authors concluded:

"Our experiments also show that fibrous talc does not cause proliferation of HTE cells or cytotoxicity equivalent to asbestos in either cell type despite the fact that talc samples contain durable minerals fibers with dimensions similar to asbestos. These results are consistent with the findings of Stanton, et al (1981) who found no significant increases in pleural sarcomas in rats after implantation of minerals containing fibrous talc."

Here again, this time in concentrated form, fibrous minerals from Vanderbilt talc did not act in the same way as asbestos. In the NTP draft review, the significance of this important study was overlooked. This study directly addresses the fibers under review in this nomination. This association, however, was overlooked.

While talc and transitional fibers are true fibers, and some (though not all) are asbestiform (see Tab B), they do differ from asbestos in ways that appear biologically important. This difference does not appear to be simply a matter of dose. Some of the differences between these fibers and asbestos fibers are discussed in the study (i.e. they tend to be thicker, they contain no iron, they are not harsh, etc.).

Many minerals (over 100) can grow in an asbestiform habit (ref. 10). In this fibrous habit, some of these minerals, such as fibrous erionite, do appear to pose a risk similar to asbestos while others, such as talc fiber, do not. Accordingly, studies involving talc fiber are of particular importance because they do suggest that asbestos pathogenicity may not simply be a function of fiber length and width (as important as fiber length and width may be).

4. While it is correct to assume significant public exposure to talc per se, it is not correct to project broad human exposure to talc containing asbestiform fibers (Vanderbilt talc).

In the 9th ROC, the NTP describes its intent to review substances **"to which a significant number of Americans are exposed".** The relevance of a nomination is therefore quite properly taken into account. If a nominated material poses little or no public exposure, there is little or no reason to list it. Accordingly, the question can be asked - how great is exposure to "talc containing asbestiform fibers"?

The NTP draft review document recognizes that standards for cosmetic grade talc are very stringent and exclude fibrous components. It is extremely unlikely that over-the-counter talcum powder contains asbestos or any appreciable (if any) talc fiber. If asbestos does appear in talc or any other commodity, it is already viewed as a human carcinogen by every risk evaluation group and regulatory agency in the country.

Absent the presence of asbestos, Vanderbilt talc with its minor talc fiber component (or any other talc of similar mineral composition) is all that is left to consider under this nomination. If exposure is broad for such talc then the nomination "talc containing asbestiform fibers" (i.e. talc fiber) might indeed be appropriate to review. Vanderbilt is aware of other talc deposits of similar mineral composition, but such talcs are rare in the United States. The most widely distributed industrial grade talc linked to this nomination is unquestionably Vanderbilt talc. What then is the exposure potential of Vanderbilt talc? How broad an exposure is it?

Exposures to Vanderbilt Talc:

Exposure to airborne Vanderbilt talc is extremely limited for a variety of reasons. The first limiting exposure factor to Vanderbilt talc is the markets into which it is sold. Vanderbilt talc is typically sold for industrial applications such as fillers in paints and ceramics. In these applications, the talc is almost always blended, encapsulated or transformed in the final product in such a way as to significantly reduce or eliminate the liberation of any mineral component in this talc (talc fiber included) into the breathing zone of American consumers.

For example, an unusual and very minor use of Vanderbilt talc recently received considerable media attention when it was incorrectly reported that children's crayons contained asbestos. The "asbestos" incorrectly reported originated from Vanderbilt talc in the crayons (10-14% loading). A review of the mineralogical confusion can be found in the OSHA Salt Lake City Laboratory's summary behind **Tab B.**

This media event ultimately drew the Consumer Product Safety Commission (CPSC) into the issue in order to determine if in fact crayons were contaminated with asbestos and whether a risk actually existed. Among many evaluations, the CPSC conducted a rough airborne exposure assessment in which it reported that:

"No fibers were found in the air during a simulation of a child vigorously coloring with a crayon for half an hour."

The CPSC concluded that crayons are safe to use, but still expressed concern over the small but observable talc and transitional fiber in the talc. One laboratory reported finding a couple anthophyllite asbestos fibers, but other labs found no asbestos in any samples. The CPSC exposure assessment may be found behind **Tab G.**

Currently, the largest application of Vanderbilt talc is in paints. Most of these paints are industrial grade paints and not common latex-based home paints. Recently the National Paint and Coatings Association completed a study on the potential for respirable crystalline silica airborne exposure during the sanding of dried paint. The results of that study showed no significant airborne exposure to respirable silica. It was concluded that the binders used in paint would tend to encapsulate particulates, making them larger and therefore less subject to inhalation (Ref. 11).

Postulating that a similar effect might reasonably be anticipated for the mineral components in Vanderbilt talc (talc fiber included), a similar exposure assessment was recently undertaken. Results showed that:

"Under the conditions of this study no detectable airborne fiber emissions during sanding of a Vanderbilt talc containing paint was found."And **"fibrous minerals were encapsulated within the paint matrix"**

This exposure assessment is considered adequate to approximate the potential for airborne fiber generation. However, a more rigorous study was recommended. In this study, a high load Vanderbilt talc containing paint (two layers) was manually sanded for one hour. A copy of the survey may also be found behind **Tab G**.

In ceramic applications (i.e. wall tile, sanitary ware, etc.), Vanderbilt talc is not only encapsulated in the finished product but often transformed during heat applications.

While consumers' exposure to talc fiber from Vanderbilt talc is marginal at best, the NTP background document correctly recognizes that exposure would likely be highest among industrial workers who mine, mill or otherwise process this talc. Unfortunately Vanderbilt has no data on fiber exposure during downstream processing (i.e. discharging talc into blending tanks at paint or ceramic tile manufacturers). It is known, however, that Vanderbilt talc is often handled in closed bulk systems. During manual handling (i.e. bag cutting and dumping), exposure does tend to be brief in duration and limited in quantity handled. Certainly it is difficult to imagine an airborne dust exposure greater than that encountered during the mining and milling of the talc.

Considerable data does exist regarding dust exposures (total dust, respirable dust and fiber levels) at the Vanderbilt talc mine and mill. A major problem with the fiber data, however, is that this data is most often all-inclusive, broad-brush fiber data. Such data include all elongated particles (i.e. aspect ratio of 3 to 1 or greater, length greater than 5

micrometers, etc.), and fails to distinguish between common elongated cleavage fragments, rods, fibers or fibers that are asbestiform. It is not possible to determine asbestiform fiber content from data presented and analyzed in this way.

In a study published in 1987 (Kelse, Thompson – copy behind **Tab G),** particle sizes and aspect ratios of airborne particulate from the Vanderbilt mine and mill were contrasted to asbestos size parameters. In the 22 air samples studied, an effort was specifically made to quantify talc and transitional fibers in the air samples (in fibers per CC).

Results indicate that there were no asbestiform fibers found and no fibers with an aspect ratio of greater than 20 to 1 were found (most asbestos fibers are greater than 20 to 1). If the average of all the talc and transitional fibers on the air filters were characterized as "asbestiform" (and all are not), the average concentration would have been 0.073 fibers/cc, viewed as any talc or transitional fiber with an aspect ratio greater than 10 to 1 (longer than 5 micrometers). A concentration of 0.743 fibers/cc is reflected for talc and transitional fibers when a 3 to 1 aspect ratio or greater (longer than 5 micrometers) criteria is applied (see Table III, p 618). The lower the aspect ratio, the less likely the talc fiber will be asbestiform. The permissible exposure limit under the OSHA Asbestos Standard is 0.1 fibers/cc **of asbestos** averaged over an 8 hour day.

Recently, additional air samples representing the dustiest areas in the mill (packing, crushing, milling) were submitted for a similar fiber analysis. Again, no asbestiform fibers were found on the air filters. Results of this analysis can be found behind **Tab G** as well.

It is likely that some exposure to airborne asbestiform talc fiber does occur both in the mine and mill and for industrial customers who further process Vanderbilt talc. Because these fibers are typically well below 1 % by weight in the various talc grades (see **Tab B**), they would not be expected to be prevalent in air samples. It is interesting to note that in OSHA's Asbestos Standard, a material is not considered an asbestos-containing material unless it contains more than 1% by weight of asbestos.

Regarding the elevated lung cancer noted among Vanderbilt talc miners, it can also be pointed out that even if this excess were dust linked, downstream exposure would be more closely linked to mill dust exposures because the processed ore is closer to the finished product. Among millers, lung cancer is not significantly elevated (ref. 7). Concern that underground miners may have been exposed to a different dust exposure (i.e. veins of concentrated fiber - for example) would not be applicable to downstream users. Such speculation is very likely unfounded, but in terms of downstream exposures, such an "even if" argument can reasonably be made. Exposures in the underground mine, incidentally, no longer exist, since it was closed a number of years ago.

In summary, available dust data do not support broad exposure to asbestiform talc fiber among Vanderbilt talc miners and millers. Asbestiform fiber exposure from Vanderbilt talc among industrial users of this talc is even less likely while the exposure of American consumers to such fibers probably doesn't exist.

CONCLUSION

Every aspect of the "talc containing asbestiform fibers" nomination is subject to serious question. The nomination is unclear as to its intent and its relevance is suspect.

This nomination is almost entirely predicated upon real or imagined mineral characterization and health data linked to Vanderbilt talc. When available studies on Vanderbilt talc are examined, the results show:

Equivocal (at best) human health data (Inverse exposure-response trends & confounding by smoking)

Negative animal data
Negative cell study data
Nonexistent inhalation exposure for the general public

It is difficult to imagine how these conclusions could possibly add up to a finding of "known human carcinogen" or even " reasonably anticipated to be a human carcinogen" under the NTP's own evaluation criteria. Only through a biased and selective review of the literature could such conclusions possibly be reached.

In Vanderbilt's original submission to the NTP (**Tab A**), it was concluded that this nomination provided an **"opportunity to help correct past errors, misperceptions and unsupported findings"**, and that the NTP would hopefully **"take advantage of this opportunity".**

Unfortunately, the NTP review process - up to this point in time - has not taken advantage of this opportunity.

Recommendations:

The NTP should drop "talc containing asbestiform fibers" as a nominated material because it is extremely ambiguous, likely to cause more confusion than it resolves; and is not necessary.

If asbestos in talc is the concern, an alternative nomination might be "talc containing asbestos" (which would be redundant since asbestos is already viewed as carcinogenic). Another alternative might be "asbestiform fibers" as a category. That nomination, however, would require a review of all minerals that might be found in nature in an asbestiform crystal growth habit – of which there are likely well over 100.

The most appropriate nomination, in my opinion, would be **mineral**-specific (i.e. fibrous erionite, sepiolite, palygorskite, talc, xonotlite – which is soluble in water, etc.), based on some supporting health evidence. In all these cases, however, exposure relevance will often be in question (as seen in the above discussion regarding talc fiber).

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R.T. Vanderbilt Company, Inc.
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June 2, 2000

Dr. C. W. Jameson
National Toxicology Program
Report on Carcinogens
MD EC-14
P.O. Box 12233
Research Triangle Park, NC 27709

RE: 10th ROC NOMINATIONS – PUBLIC COMMENT
Talc (containing asbestiform fibers)

Dear Dr. Jameson:

R. T. Vanderbilt Company, Inc. ("Vanderbilt") and its wholly-owned subsidiary, Gouverneur Talc Company, are engaged in the mining, milling and marketing of industrial talc that is used primarily in the paint and ceramic industries. Vanderbilt appreciates the opportunity to comment on the captioned NTP nomination. We believe that the available evidence does not support the need for a separate entry for talc containing asbestos or asbestiform fibers. Such an entry would suggest to the public that this is a real and far reaching exposure potential, when in reality it is extremely rare (if it occurs at all). While talc containing asbestos or asbestiform fibers may be perceived as a substantial cancer threat, in reality, such a threat is not reasonably supported. Further, there is no need to consider the carcinogenicity of asbestos, since the latter is already listed. Vanderbilt's comments are divided into two main areas: Nomenclature and Justification. We have also appended several reference documents which are organized under general topic tabs as well.

NOMENCLATURE

The entry "talc containing asbestiform fibers" is misleading. If the entry means the mineral talc contaminated with "asbestos," it would be more clearly expressed as "talc containing asbestos". That change would also be consistent with the way most government agencies and mineral scientists describe this mineral category. For example, the Occupational Safety and Health Administration (OSHA) uses the phrase "talc containing asbestos" in its current Permissible Exposure Limits Tables (OSHA ref. 1, Tab 1). The American Conference of Governmental Industrial Hygienists (ACGIH) expresses the exposure in the same way in its Threshold Limits Values for Chemical Substances and Physical Agents (ACGIH ref. 2, Tab 1). The Environmental Protection Agency (EPA) also addresses the exposure as "asbestos" (ref. 3, tab 1).

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The NTP currently lists asbestos as a known human carcinogen. Accordingly, any material containing asbestos would reasonably be assumed to pose a carcinogenic risk, depending upon the amount of asbestos involved, the duration of exposure, the type of asbestos involved, the route of entry, etc. The origin of this entry is understood to be Supplement 7 (1987) to the International Agency for Research on Cancer (IARC) which characterizes the exposure as "talc containing asbestiform fibers". However, this IARC reference is neither up to date nor accurate. The studies noted in Supplement 7 have been superseded by a more advanced understanding of mineral nomenclature and biological issues concerning talc and asbestos.

The word "asbestos" is a commercial term applied to six specific minerals, but only when they exhibit an "asbestiform" crystal growth structure or "habit". The asbestiform crystal growth pattern is extremely rare in nature, and the six minerals are far more abundant in their nonasbestiform habit. When these six minerals do not exhibit asbestiform crystal growth they are not classed as asbestos. In their far more common nonasbestiform habit some of these minerals are called by other names even though chemically and structurally (internal structure) they are the same mineral. (See references 4 to 9 tab 2 and references 10 and 12 Tab 3 for a more complete discussion.) The amphibole minerals tremolite, anthophyllite and actinolite are called by the same name, regardless of their crystal growth habit.

In addition to the six asbestos minerals, many minerals (including the mineral talc itself) can be found in nature in an asbestiform "habit" (Steel et al, ref 5, Tab 2). Such occurrences, however, are rare. When growing in this habit, these minerals share the same basic external crystal growth structure as the six asbestos minerals, but differ in other respects (physio-chemical properties, harshness, durability, etc.). It is therefore misleading to use the term "asbestiform" as a synonym for asbestos. "Asbestiform" refers only to a crystal growth habit. Mineral scientists from academia, government and industry have taken great pains to describe these distinctions (see references 4 to 9, Tab 2 and 10 and 11, Tab 3), but confusion still exists.

As pointed out by Campbell et al (U.S. Dept. of Interior, ref. 4, Tab 2), "Precise definitions acceptable to mineral analysts, regulatory personnel, and medical scientists are essential because of the present lack of conformity in terminology concerned with measuring and controlling asbestiform particulates and their related health effects". The meaning of terms like "fiber", "asbestos" and "asbestiform" are unfortunately unclear to many health investigators. Such ambiguity can lead to misleading exposure characterization in health studies involving elongated particles.

One series of studies, prominently referenced in the NTP cited IARC supporting monograph, exemplifies error. These references involve early mortality studies conducted by Kleinfeld, et al (ref. 38, tab 5) and NIOSH (Brown, et al ref. 36, tab 5) on upstate New York tremolitic talc miners and millers. The NIOSH study exclusively involves Vanderbilt talc miners and millers.

In these studies NIOSH incorrectly characterized nonasbestiform amphibole cleavage fragments as asbestos, as they had previously done in another study involving amphibole

minerals (Homestake Gold mining study – see ref. 24, tab 5 pp. 38-39). Much of the concern involving asbestos in talc originated from this erroneous characterization by NIOSH. Over the years, however, this complex mineral mix has been studied by many highly regarded analysts who repeatedly confirmed the absence of asbestos in this talc (see references 10 to 14, tab 3 and reference 17, tab 4).

The nonasbestiform amphibole controversy associated with these talc worker studies spanned several decades and was ultimately the center of a protracted OSHA rulemaking process. This rulemaking culminated in an OSHA final rule in 1992 which stated that substantial evidence is lacking to conclude that nonasbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health risks as asbestos (OSHA ref.. 8 tab 2). The complete OSHA record, which includes extensive mineral nomenclature discussion and health study reviews pertinent to this NTP review can be obtained under Docket H-033-d of the Occupational Safety and Health Administration; 200 Constitution Avenue N.W.; Room N2625; Washington, DC (OSHA ref.. 8, tab 2).

In its rulemaking, OSHA recognized the key mineral distinctions discussed above and specifically acknowledged that the mineral composition of Vanderbilt talc was in fact correctly stated on the company's Material Safety Data Sheet and that this talc did not contain asbestos (MSDS ref. 15, tab 3). Prior to the final OSHA rulemaking, a more accurate understanding of the actual composition of this talc was recognized by OSHA's own laboratory (Crane letter ref. 11, tab 3). This is the same talc incorrectly characterized in the IARC monograph as "asbestos-containing". We urge that the NTP not perpetuate this error.

If any particular nonasbestos mineral caused the same health effects as asbestos, it would certainly be important to regulate and control that mineral exposure just as asbestos is controlled. However, we should not confuse cause and effect associations and "mechanism" studies designed to predict risk by obscuring (rather than clarifying) the nature of the exposure. For this reason throughout the years, Vanderbilt and others have repeatedly appealed to health researchers to use proper mineral nomenclature when addressing health effects. As discussed by Dr. Campbell (supra), it is critically important to call things what they are.

If the intent of the "talc containing asbestiform fibers" entry is to characterize and evaluate the carcinogenic risk of talc containing asbestos, the entry should specifically say "talc containing asbestos". Alternatively, the entry might be deleted altogether since asbestos is already listed as a known human carcinogen. The IARC references underlying the nomination suggest that actual "asbestos" exposure is being discussed (valid characterization or not).*

* If the intent is to address any mineral in the asbestiform habit, then risk information for asbestiform minerals other than asbestos would need to be addressed and be reasonably shown to have a carcinogenic effect (such as that shown for asbestos).

JUSTIFICATION

Should the NTP continue with the entry "talc containing asbestiform fibers" as a known human carcinogen, justification for that entry needs to be addressed. Presently, there is scant support for such an entry. A review of the 1987 IARC Supplement monograph in which this mineral combination was characterized as a known human carcinogen reflects the following supporting references and arguments.

a. Asbestos was found in assorted, off-the-shelf cosmetic talcs in the 1970's (Rohl, et al), posing a risk to general consumers and supporting the perception that asbestos is a common contaminant in talc.

b. Asbestos was reported by NIOSH in New York State industrial grade tremolitic talc, posing a risk to miners and millers as well as industrial users of this talc (ceramics, paint, etc.). See Brown, et al, ref. 36, tab 5.

c. The asbestos NIOSH reported in New York talc (tremolite and anthophyllite specifically) was said to be the etiologic agent in the elevated lung cancer observed in these talc miners (Brown, et al ref. 36, tab 5). Earlier studies of New York talc miners from the same region showed a similar lung cancer excess (Kleinfeld, ref. 38, tab 5).

d. Four case reports of mesothelioma were said to be linked to upstate New York talc mining (Vianna, 1981).

Each of these references is addressed below.

A. Asbestos was found in some cosmetic talcs and may therefore be a common contaminant in talc.

Reports of trace asbestos found in some off-the-shelf samples of cosmetic talc appeared in the 1970's through the work of Mt. Sinai researchers (Rohl, et al). At that time the principal researcher (Rohl) also found asbestos in New York State tremolitic talc (Vanderbilt talc) in support of the NIOSH work. These findings are incorrect (Langer ref. 17, tab 4).

Given the lack of definitional specificity and the less rigorous analytical protocols that existed at the time (Langer ref. 17, tab 4 and National Bureau of Standards ref. 22, tab 6), the accuracy of these early reports of contamination is unclear. Petitions to require asbestos labeling on cosmetic talc were denied by the Consumer Product Safety Commission (CPSC) with the support of the Food and Drug Administration (FDA) due to concerns about the reliability of these reports (see CPSC ref. 21, tab 4). Analytical deficiencies in these reports were detailed in the National Bureau of Standards' Special Publication 506 and supporting documentation (see also Krause, et al, ref. 23, tab 4).

According to mineral scientists, the notion that asbestos is commonly found in talc ore deposits is not correct. The occurrence of asbestos in talc ore bodies is in fact rare, and is essentially limited to serpentine asbestos (chrysotile). In addition, upgrades in federal and industry talc purity standards as well as quality control procedures make asbestos contamination in talc rare to nonexistent. The Zalenski, et al, paper entitled "Talc: Occurrence, Characterization, and Consumer Applications" discusses these considerations more fully (see Zalenski, et al, ref 18, tab 4), as does the National Bureau of Standards' Special Publication 506 referenced above. If this reported contamination is of critical concern to the NTP, it is strongly encouraged to obtain additional confirmation from knowledgeable mineral scientists.

B. Asbestos was reported in Vanderbilt talc and thus poses an asbestos risk to the miners and millers of this talc as well as downstream users of this talc.

The absence of asbestos in Vanderbilt talc is discussed above. If references 10 through 15, tab 3, and ref. 16, tab 4 do not adequately confirm the absence of asbestos in this talc, we urge the NTP to review complete analytical documents which were submitted to OSHA. (A listing of all the analytical reports available to us, with basic results summarized from 1973 through 1990, are included at ref. 16, tab 3). Clarification that the minerals reported as asbestos by NIOSH (tremolite and anthophyllite) were in fact not asbestos is important since the mortality studies of upstate New York talc minors and millers are also relevant to the NTP evaluation.

The only truly fibrous or asbestiform particulate in Vanderbilt tremolitic talc (the sole producer of New York state talc since 1974) is a minor quantity of talc fiber, and to a lesser degree a very rare talc/amphibole mixed fiber. The genesis and composition of this rare mixed fiber remains undetermined after considerable study; but, it is known that these fibers are intergrown at the lattice level and can therefore not be separated. Although it has been asserted that talc fiber may be found in any talc if one looks long enough, these fibers are relatively easy to find in Vanderbilt talc. However, these fibers are still a very minor component. An analysis by weight percent of various grades showed the average highest grade % to be 0.00788 for combined talc fiber and mixed talc/amphibole fiber (Van Orden ref. 20, tab 4). In accordance with OSHA's Hazard Communication Standard and/or Asbestos Standard, such a product would not be considered asbestos-containing even if talc fiber were regulated as asbestos (which it isn't). Some of the confusion linked to the perception that asbestos exists in talc comes from the observation of these rare fibers. Health investigations involving talc fiber will be discussed below (Wylie, Mossman at ref. 25, tab 5).

It must also be recognized that if the amphibole in Vanderbilt talc (especially tremolite) was asbestos, the health effects discussed in the next section would be dramatic, since upwards of 50% of the ore and product contains these minerals. Tremolite asbestos, for example, appears to be a rather potent carcinogen, as evidenced by limited exposures to it (below a 10% content) and the prevalence of carcinogenic response associated with the mining and milling of vermiculite (Libby, Montana, see ref. 24, tab 5, pp 18-19). Animal studies also clearly reflect the elevated carcinogenic potential of tremolite asbestos (see ref. 24, tab 5, pp 22-31).

C. "Asbestos" reported in the NIOSH mortality study of Vanderbilt talc miners and millers is said to be responsible for the excess lung cancer observed in this cohort. A similar excess was observed earlier by Kleinfeld et al in miners from the same area. That is, exposure to this talc causes lung cancer.

In tab 5, we have included every health study known to us involving Vanderbilt talc. The references are preceded by a summary of these studies (Pictorial Exhibit, ref. 24 pages 42 to 47, tab 5). The animal and cellular studies include (in several cases) component concentrates (tremolite and talc fiber) tested against asbestos. Most of the studies involve epidemiological studies of our talc miners and millers. We believe that few other (if any) worker populations or mineral exposures have been studied as extensively.

Though rare, the presence of talc fiber noted in this talc may understandably be a source of concern (beyond the issue of what is and is not asbestos). In this regard, a careful review of Wylie, Mossman (ref. 25, tab 5) is helpful. In this cellular study, the authors conclude: "Our experiments also show that fibrous talc does not cause proliferation of HTE cells or cytotoxicity equivalent to asbestos in either cell type despite the fact that talc samples contain durable mineral fibers with dimensions similar to asbestos. These results are consistent with the findings of Stanton et al (1981) who found no significant increases in pleural sarcomas in rats after implantation of materials containing fibrous talc." The authors also point out the consistency of these findings with another negative tumor animal study involving Vanderbilt talc and epidemiological studies involving Vanderbilt talc (discussed below). The cellular study involved a talc fiber concentrate that is not reflective of any real world exposure known to us.

Cohort mortality studies of upstate New York talc miners and millers are also critical because they directly address human exposure and response. While animal and cellular studies involving carcinogenicity may provide a more controlled evaluation (all are negative for Vanderbilt talc – see Stanton, ref. 34 and Smith, ref. 37, tab 5 & McConnell, ref 39 tab 5), few worker populations have been as extensively studied as Vanderbilt talc miners and millers. Today, a two to threefold excess in lung cancer mortality persists in this cohort (to 1990 at least). However, more recent mortality studies of these talc miners and millers do not support a dust etiology (Delzell, ref. 26; Gamble, ref. 27; Lamm, ref. 30-31; Stille, ref. 32, in tab 5).

The causal association to tremolitic talc dust suggested by Kleinfeld (ref. 38, Tab 5) and NIOSH (Brown ref. 36, Tab 5), is not supported in subsequent, larger, more discriminating studies (Delzell, ref. 26 and Gamble, ref. 27 in particular). Today, these miners and millers are no longer considered exposed to asbestos and most agree that the observed excess lung cancer is no longer considered linked to the workplace.

Earlier mortality studies (both pro and con for a dust causal link) do suffer from many methodological shortcomings. These shortcomings include the small study population involved, the lack of dust exposure and smoking histories and proper internal controls (case - control evaluation), the lack of prior work histories and many unsupported notions which contradict

basic cause/effect principals (i.e., Hills criteria in determining causation). IARC, had only these earlier studies to cite in its review.

While it has been said that virtually all epidemiological efforts have shortcomings, the most recent work by Delzell and Gamble strive to address earlier study weaknesses. In both studies, the researchers conclude that the excess lung cancer observed is unlikely linked to the dust exposure principally because they demonstrated that smoking could account for the excess and there is no dose response relationship demonstrated. In fact, the latter is inverse in relation to observed nonmalignant respiratory disease mortality. The frequently referenced NIOSH study merely recorded the excess lung cancer, incorrectly found "asbestos" where it did not exist and concluded that this "asbestos" was the logical cause of the excess. Although time from first exposure to death did support a causal link, other key causality considerations were not properly addressed (smoking history, exposure by either tenure or dust levels, consistency with other findings, etc.). References 40 through 47 and 49 to 51, tab 6 contain critiques which address several of the cohort studies (principally the Brown, et al, NIOSH study). These critiques (the Gamble critique in particular – ref. 40, tab 6) provide compelling criticism of the NIOSH work.

Reference 33, tab 5 reflects a mortality study of Vanderbilt talc users ("population at risk") underwritten by the National Paint and Coatings Association (NPCA) and published in 1981. This study finds no excess pulmonary cancer in over 16,000 paint workers from 32 plants in the United States. A cover sheet attached to this reference explains the very high use of Vanderbilt talc in the paint industry (which persists to this day).

At present, the predominant use of Vanderbilt talc is in paint manufacturing. Ceramic use has dramatically declined due to process upgrades in the ceramics industry allowing for the use of cheaper raw materials. There are no other Vanderbilt talc user health studies known to us. One pottery worker study referenced by NTP in support of it's review of pure talc (Thomas, et al) suggests excess lung cancer among workers exposed to pure talc (among other things) but not among a subpopulation of these pottery workers earlier exposed to tremolitic talc (origin of the talc unclear). This study gives no support to a link between tremolitic talc and cancer.

It can reasonably be assumed that few if any downstream users of tremolitic talc would experience dust exposures greater than those experienced by our own miners and millers. If cancer can not be demonstrated in Vanderbilt talc miners and millers, or in direct animal testing involving this talc, a significant cancer risk to downstream users is difficult to imagine.

While Vanderbilt talc should not be viewed as asbestos containing or cancer causing, there is no question that overexposure to this tremolitic talc (or any mineral dust) can result in nonmalignant respiratory disease. We believe that exposure to all talc has been reasonably linked to the development of pleural plaques and we have seen this in our own talc workers. There is no clear evidence, however, that pleural plaques promote the evolution of pleural tumors or even pulmonary impairment such as diminished pulmonary function (Boehlecke ref. 52, tab 7).

Reference 52, tab 7 contains comments submitted to the OSHA docket (1990) concerning the regulation of nonasbestiform amphiboles by Brian Boehlecke M.D. Dr. Boehlecke is a pulmonary consultant who has reviewed the pulmonary condition of Vanderbilt miners and millers over the last eighteen years. We agree with Dr. Boehlecke's observations regarding pleural plaques and parenchymal pneumoconiosis ("talcosis"). Dr. Boehlecke has reviewed numerous talc studies and offers some comparative comments regarding the prevalence and type of pulmonary abnormalities noted in tremolitic talc workers contrasted to nontremolitic talc workers. A review of this reference is highly recommended. The current pulmonary status is consistent with those reported by Dr. Boehlecke in 1990.

An interesting study was conducted in the mid 1980's by Dr. Steven Lamm during a follow-up cohort study. In this study, Dr. Lamm compared rates for lung cancer deaths and pneumoconiosis for Vanderbilt talc workers (said to be exposed to asbestos by NIOSH) and Vermont talc workers (said not to be exposed to asbestos by NIOSH) with at least one year of exposure. Cohort comparisons of this sort can be problematic for many reasons, but these groups did share many similarities (the cohort size was approximately similar, the years of exposure were similar, overall dust levels were similar, quartz exposure (trace) was similar in both dusts, etc.). In this comparison, the lung cancer rate was essentially the same and the rate for nonmalignant respiratory disease was slightly higher in the Vermont cohort. This comparison can be further reviewed in reference 31, tab 5 in a preliminary report entitled "Absence of Lung Cancer Risk from Exposure to Tremolitic Talc" February 14, 1986 pages 21 through 23.

While nonmalignant respiratory disease and other abnormalities linked to talc are not the subject of this NTP evaluation, we have addressed them because of the mistaken assumption by some that such abnormalities are only linked to asbestos or are a precursor to pleural cancers (i.e., mesothelioma).

D. Cases of malignant pleural mesothelioma have been reported for individuals exposed to tremolitic talc mining and milling.

This IARC reference is problematic. In the most recent cohort follow-up (Delzell, 1995 – ref 26, Tab 5), two mesothelioma cases were reported, but neither was considered linked to talc exposure. The first case was reported by NIOSH (Brown et al ref. 36, Tab 5) and was also discounted because the latency was too short (diagnosed 15 years after first talc exposure). The second case died in 1986 and worked 6 months at the mine in the Engineering office as a surveyor in 1948. After this brief encounter in 1948, he then worked many years repairing home heating systems.

Four case studies are referenced in the IARC supplement (Vianna, et al) but are not sufficiently detailed in the text to determined if the case referenced in the NIOSH study was included. The other cases, unknown to us, may have involved exposures in other area mines (no longer in operation), may have been linked to other asbestos exposures or may have been misdiagnosed. It appears that the 1981 paper studied the general population in selected New

York State counties and was not specific to talc mining in the region. Interpretive problems associated with case study reports are well understood and frequently render such reports anecdotal at best. In addition, given experience with actual asbestos exposure (especially asbestos amphibole exposure), adequate latency in the Vanderbilt cohort could have reflected cases which would show an association by the end of 1989 (vital status cut off of the latest study) - although a latency beyond 40 years would be preferable.

There is much controversy regarding the cause and ("mis") diagnosis of mesothelioma, and the NTP panel members are no doubt familiar with these issues. Tab 8 contains relevant papers which address these problems. Given the status of available data on mesothelioma in general and Vanderbilt talc specifically, one cannot reasonably conclude that a cancer association exists.

In summary, if a review of "talc containing asbestos" or "talc containing asbestiform fibers" is undertaken, we request that the NTP recognize the shortcomings of the 1987 IARC Supplement and evaluate the category based upon all available studies and documentation. Considerable confusion obviously exists in this area. The unfortunate link between talc and asbestos has been highly publicized and tends to be an emotional issue. Moreover, some groups (i.e. NIOSH) have taken strong positions (especially regarding Vanderbilt talc) and objectivity may be challenged. For these reasons we believe that it is of particular importance that the weight of all available evidence be carefully considered. The NTP has an opportunity to help correct past errors, misperceptions and unsupported findings. We hope it will take advantage of this opportunity.

Respectfully submitted,

R.T. VANDERBILT COMPANY, INC.

By: John W. Kelse

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LABORATORY

June 12, 2000

BACKGROUND INFORMATION REGARDING THE ANALYSIS OF INDUSTRIAL TALCS

When OSHA first promulgated its expanded asbestos standard in 1972, it included what was understood to be the occupationally important asbestos minerals. The term asbestos is not a proper mineralogical term. It has been applied for thousands of years to minerals which were obviously fibrous and could be used for spinning and weaving, fireproofing and for composite materials in clays and pottery. It came to be applied to any of the minerals having this gross appearance and use. By the time OSHA promulgated its standard, the commercial definition was limited to chrysotile, Amosite (grunerite asbestos), crocidolite, anthophyllite asbestos, tremolite asbestos and actinolite asbestos. (29 CFR 1910.1001(b)). These were the minerals that were encountered in occupational asbestos exposures.

In addition to these six minerals, there are over one hundred other minerals known to exist in the asbestiform habit (Walter Bank, private communication , 1978). These minerals are not properly known as "asbestos." The fibers contained in these minerals have the same general growth habit and shape as the fibers of the six asbestos minerals. They can be easily parted along their length, and they generally have a high tensile strength both of which give rise to fibers with very high aspect ratios (ratio of the length to with of individual fibers). Without careful mineralogical identification, some of these minerals can easily be misidentified as one of the six asbestos minerals. In addition to any confusion brought to the table by non-asbestos asbestiform minerals, some of the asbestos minerals grow in non-asbestiform habits. When crushed, these minerals will form cleavage fragments which may be much longer than they are wide owing to preferential parting along a preferred axis. These are fibers. But, they are not asbestiform. Fibers of asbestos are asbestiform because they grew that way, not because they were crushed to make them fibrous. Some minerals have different names for the various growth habits they possess. In the case of tremolite, actinolite, and anthophyllite there is no separate name given. The asbestiform varieties must be identified by using the adjective, asbestiform or asbestos, (e.g. asbestiform tremolite).

Beyond the morphological ambiguity, minerals do not occur in exactly the same chemistry throughout the world, or even across an individual deposit. It is possible, with adequate representative samples, to identify a particular mine from which a mineral was removed. The elements present, the temperature, pressure, time, and exposure all contribute to the composition and structure of a given mineral. Along with chemical variations, there also exist structural differences and accidents which occur because of particular conditions present at the formation of the mineral and through subsequent time. A mineral once formed in a process may be changed either rapidly or slowly to another mineral given a proper set of circumstances.

Historically, it has been the analyst's task to sort out, identify and classify minerals according to

a set of optical criteria. The results of these optical tests performed in a polarizing microscope, will identify most minerals. It is not always possible, nor desirable, to perform every test for every particle because the particle is too small to give a result, or only some tests are required where the mineral identification is limited to a small number of possibilities.

This is the case with the asbestos minerals. When determining the type and percent of commercial asbestos minerals, in a product to which it was intentionally added, it is only necessary to determine two of the three major indices of refraction, the sign of elongation, the angle of extinction, and observe that the mineral is birefringent. Where only commercial asbestos is present, there are no serious interferences and this limited set of information is adequate to identify the presence of chrysotile, Amosite, crocidolite, tremolite asbestos, actinolite asbestos and anthophyllite asbestos. If other, asbestiform minerals are present, or if non-asbestiform cleavage fragments of one or more of the asbestos minerals is present, an analyst may encounter difficulty in determining which fibers are asbestos and which are not.

Relatively recently, x-ray diffraction, transmission electron microscopy, microprobe analysis, and scanning electron microscopy have been added to the arsenal of the mineral analyst. These tools allow the analyst to investigate the crystal structure and the chemical content of minerals. They also introduce a new set of confounding information which can confuse and mislead an analyst trained mainly to look for commercial asbestos minerals.

The tremolitic industrial talcs such as those found in New York present a difficult analytical problem. The material has a high component of non-asbestiform tremolite, some mostly non-asbestiform anthophyllite, some massive and some asbestiform talc, some quartz, and some intermediate or transitional asbestiform mineraloids along with traces of other minerals.

This mineral assemblage presents two red herrings for asbestos analysts. This group of products has cleavage fragments of non-asbestos tremolite and anthophyllite which, while meeting the definition used for phase contrast counting (aspect ratio longer than or equal to 3 to 1 and longer than or equal to 5 micrometers), are not covered by the OSHA definition of asbestos. Secondly, there are asbestiform fibers in the products which range in composition from nearly that of anthophyllite to talc. Except for a very few fibers occasionally found to be anthophyllite asbestos, these fibers are generally not covered by the OSHA asbestos standard.

The first problem is complicated by two factors. The first is that cleavage fragments are not covered by federal standard while the most common method used by NVLAPS laboratories requires the inclusion of cleavage fragments. The second is that it may not be possible to determine whether an individual fiber is a cleavage fragment or an asbestiform fiber if it has an aspect ratio less than about 20 to 1. Asbestiform minerals usually have average aspect ratios in excess of 100 to 1, while cleavage fragment distributions typically have mean aspect ratios below 10 to 1. Some help is afforded by the information in OSHA method ID-191 or of Bureau of Mines Information Circular IC8715. These document some of the analytical clues. A determination for a mineral is usually made if the average aspect ratio appears to be very large or the cleavage fragments are generally free of longitudinal striations or they are acicular or other non-asbestiform fiber shape.

The second problem leading to false identification of asbestos in these talcs is the presence of the

asbestiform intermediate or transitional fibers. It is thought that these fibers were once anthophyllite and have undergone a mostly completed retrograde metamorphosis to talc. Their appearance is strikingly asbestiform. The selected area diffraction patterns obtained in the usual manner for asbestos analysis appear almost like those of anthophyllite asbestos. This is due to the peculiar crystal structure of the talc in this mineraloid. If one looks directly at the crystal structure using high resolution electron microscopy, the structure of the fiber can be seen to consist of randomly distributed chains of amphibole (anthophyllite), talc, and pyroxene chains. The individual fibrils (smallest asbestiform fiber structure) are constructed of a fine mixture of minerals on a scale too fine to be resolved by a light microscope. This particular arrangement of atoms gives a diffraction pattern with enough amphibole character to mis-identify it as anthophyllite.

The same structure also lead to erroneous identification of the chemistry. In pure end-member talc, there are 6 magnesium atoms for every 8 silicon atoms. In the magnesian end member for anthophyllite, there are 7 magnesium atoms for every 8 silicon atoms. The EDX spectra for such fibers are almost indistinguishable by observation alone. It is only by very careful calibration and quantitative analysis that an analyst is able to differentiate these intermediate fibers from anthophyllite. The average analysis for these fibers puts the concentration of magnesium at between 6.5 and 6.8 magnesium atoms per 8 silicon atoms. A fiber having a magnesium population at or above 6.8 would be considered to be anthophyllite if it has a corroborating Selected Area Electron Diffraction (SAED) pattern, with an internal standard (gold), to be indexed as anthophyllite.

It is generally observed that PLM laboratories do not always perform the TEM because they see the cleavage fragments and call them asbestos. Conversely, TEM laboratories do not perform the PLM and call the fibers seen anthophyllite with some tremolite.

When the techniques are combined, it is noted that the asbestiform fibers have indices of refraction almost exclusively below 1.592. Also, there are some cleavage fragments of tremolite having indices of refraction above that in the range 1.620 and very occasionally a fiber appearing to be asbestiform with indices of refraction in the range of 1.620 which is probably anthophyllite. It is rare to see a fiber clearly identifiable as anthophyllite in the PLM.

Conversely, when viewed in the TEM, almost all of the fibers appear to be anthophyllite using the usual techniques of asbestos analysis applied to the asbestos abatement industry. The diffraction patterns are sufficiently similar that using only pattern recognition, a mistake is made. The usual check on this mis-identification is to look at the EDX chemistry. It is so similar to the anthophyllite that it only confirms the identification of anthophyllite.

What TEM says is there is denied by PLM. The cure, in this case, is careful analysis. Pattern recognition for SAED contains a number of pitfalls which should be avoided by indexing wherever practical. Whenever general mineralogical materials might be present beyond the commercial asbestos minerals, it is very important to step beyond the short set of identification criteria and fully identify the fibers present.

In summary, the difficulty and novelty of the minerals present and the complexity of the regulatory environment led to an identification of asbestos where none exists. The relative risk of exposure to non-asbestos asbestiform minerals was not addressed in any of this discussion and inclusion or non-inclusion of any mineral should not be taken as a statement of risk by OSHA.

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The Materials Characterization Specialists

November 22, 2000

Mr. John W. Kelse
R. T. Vanderbilt Company, Inc.
30 Winfield Street
Norwalk, CT 06856-5150

RE: PLM Evaluation of Talc Samples
RJ Lee Group Job No.: LSH006444

Dear Mr. Kelse:

RJ Lee Group has completed the analysis of several samples of talc. The procedure used for these analyses is based on a procedure developed by Dr. Ann Wylie. Basically, a known mass of sample is placed on a clean glass slide to which is added several drops of 1.598 refractive index oil. Twenty percent of the slide is examined in a polarizing light microscope; the dimensions of every particle with an aspect ratio of at least 3:1 (length to width) are recorded. The minerals were identified as talc, tremolite, anthophyllite, or "transitional" according to the following system:

Mineral	α, RI	γ, RI
Talc	< 1.598	≤ 1.598
Transitional	< 1.598	> 1.598
Amphibole	≥ 1.598	> 1.598

In addition, the particles were classified as "fiber" or "cleavage" using a consensus definition. Particles classified as "fiber" are asbestiform and show evidence of high aspect ratio, bundles, splayed ends, and curvature. Splayed ends are generally indicative of bundles of asbestiform fibers. There were several high aspect ratio transitional particles which did not meet the consensus definition of asbestiform (generally not displaying evidence of curvature or splayed ends).

Seven samples were submitted for analysis (NYTAL 100, NYTAL 200, NYTAL 300, NYTAL 400, NYTAL 3300, NYTAL 7700, and IT-3X). This preliminary report discusses the data generated on the NYTAL 100 and NYTAL 300 samples, with partial analyses of the other samples. Analyses of the remaining samples are progressing and will be reported as they become available.

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Table 1 shows the concentration of the particles with aspect ratios of at least 3:1. The table shows two measures of concentrations, particles/mg of sample and weight percent. In the samples, the particle type with the largest concentration is tremolite. Very few anthophyllite particles were observed in any sample.

Table 2 shows the concentration of all asbestiform fibers observed in these samples. In the samples, only talc fibers were observed to be asbestiform; all other particles are cleavage fragments. Very few asbestiform fibers were observed with an aspect ratios less than 5:1.

Figure 1 compares the average lengths for the principal mineral components of the Nytal products. Figures 2 and 3 show the average width and aspect ratios for the sample products. Figure 4 shows the particle number concentration and particle weight percent for each analyzed product.

RJ Lee Group, Inc. is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP), New York Department of Health Environmental Laboratory Approval Program (ELAP), and by the American Industrial Hygiene Association (AIHA). This report relates only to the items tested and shall not be reproduced except in full. NVLAP accreditation does not imply endorsement by NVLAP or any agency of the US government. These results are submitted pursuant to RJ Lee Group's current terms and conditions of sale, including the company's standard warranty and limitation of liability provisions. No responsibility or liability is assumed for the manner in which the results are used or interpreted. Unless notified in writing to return the samples covered in this report, RJ Lee Group will store the samples for a period of 30 days before discarding. A shipping and handling fee will be assessed for the return of any samples.

If you have any questions, please feel free to call me.

Sincerely,

Drew R Van Orden

Drew R. Van Orden, PE
Senior Scientist

Table 1. Concentration of All Mineral Particles With An Aspect Ratio of At Least 3:1

Product	Slide	Mineral	particle/mg			Particle Wt, %		
			3:1 - 5:1	≥ 5:1	≥ 3:1	3:1 - 5:1	≥ 5:1	≥ 3:1
Nytal 100	1	Tremolite	353	839	1,193	4.39	2.02	6.41
		Anthophyllite		12	12		< 0.01	< 0.01
		Transitional	16	265	281	0.19	3.09	3.28
		Talc	16	189	205	0.21	0.31	0.52
	2	Tremolite	289	1,042	1,331	4.09	2.69	6.77
		Anthophyllite		6	6		0.01	0.01
		Transitional		66	66		0.37	0.37
		Talc	15	114	129	0.03	0.08	0.11
	3	Tremolite	375	1,288	1,663	6.78	3.58	10.35
		Anthophyllite		4	4		< 0.01	< 0.01
		Transitional	6	101	107	0.06	1.03	1.09
		Talc	2	230	233	< 0.01	0.14	0.15
Nytal 300	1	Tremolite	843	3,638	4,481	1.04	1.29	2.33
		Anthophyllite		12	12		0.01	0.01
		Transitional	12	341	353	0.07	0.57	0.64
		Talc		1,056	1,056		0.37	0.37
	2	Tremolite	18	3,395	3,412	< 0.01	0.63	0.64
		Anthophyllite						
		Transitional		272	272		0.31	0.31
		Talc		727	727		0.08	0.08
	3	Tremolite	361	3,453	3,814	0.44	1.24	1.68
		Anthophyllite		4	4		< 0.01	< 0.01
		Transitional	8	261	269	0.01	0.35	0.36
		Talc	16	1,044	1,060	0.03	0.17	0.20

Table 1. Concentration of All Mineral Particles With An Aspect Ratio of At Least 3:1 (continued)

Product	Slide	Mineral	particle/mg			Particle Wt, %		
			3:1 - 5:1	≥ 5:1	≥ 3:1	3:1 - 5:1	≥ 5:1	≥ 3:1
Nytal 3300	1	Tremolite	337	4,376	4,713	0.28	0.89	1.17
		Anthophyllite		18	18		0.01	0.01
		Transitional	18	285	302	0.24	0.55	0.79
		Talc		1,318	1,318		0.35	0.35
Nytal 7700	1	Tremolite	123	4,486	4,609	0.04	0.27	0.31
		Anthophyllite		11	11		< 0.01	< 0.01
		Transitional		277	277		0.33	0.33
		Talc	5	2,050	2,050	< 0.01	0.15	0.15
Nytal 200	1	Tremolite	166	1,748	1,914	0.49	1.80	2.30
		Anthophyllite						
		Transitional	13	145	158	0.08	0.72	0.79
		Talc	26	950	977	0.11	0.63	0.74
Nytal IT-3X	1	Tremolite	206	1,310	1,516	1.20	1.52	2.73
		Anthophyllite	4	101	105	0.06	0.02	0.09
		Transitional	110	1,117	1,226	0.84	3.45	4.29
		Talc	35	4,844	4,880	0.48	2.20	2.68

Table 2. Concentration of All Asbestiform Mineral Fibers With An Aspect Ratio of At Least 3:1

Product	Slide	Mineral	Fiber/mg			Fiber Wt, %		
			3:1 - 5:1	≥ 5:1	≥ 3:1	3:1 - 5:1	≥ 5:1	≥ 3:1
Nytal 100	1	Talc		104	104		0.02	0.02
	2	Talc		60	60		0.05	0.05
	3	Talc		128	128		0.06	0.06
Nytal 300	1	Talc		707	707		0.29	0.29
	2	Talc		477	477		0.05	0.05
	3	Talc		879	879		0.11	0.11
Nytal 3300	1	Talc		1,099	1,099		0.32	0.32
Nytal 7700	1	Talc		1,895	1,895		0.13	0.13
Nytal 200	1	Talc	4	381	385	< 0.01	0.30	0.31
Nytal IT-3X	1	Talc	13	2,961	2,974	0.02	1.76	1.78

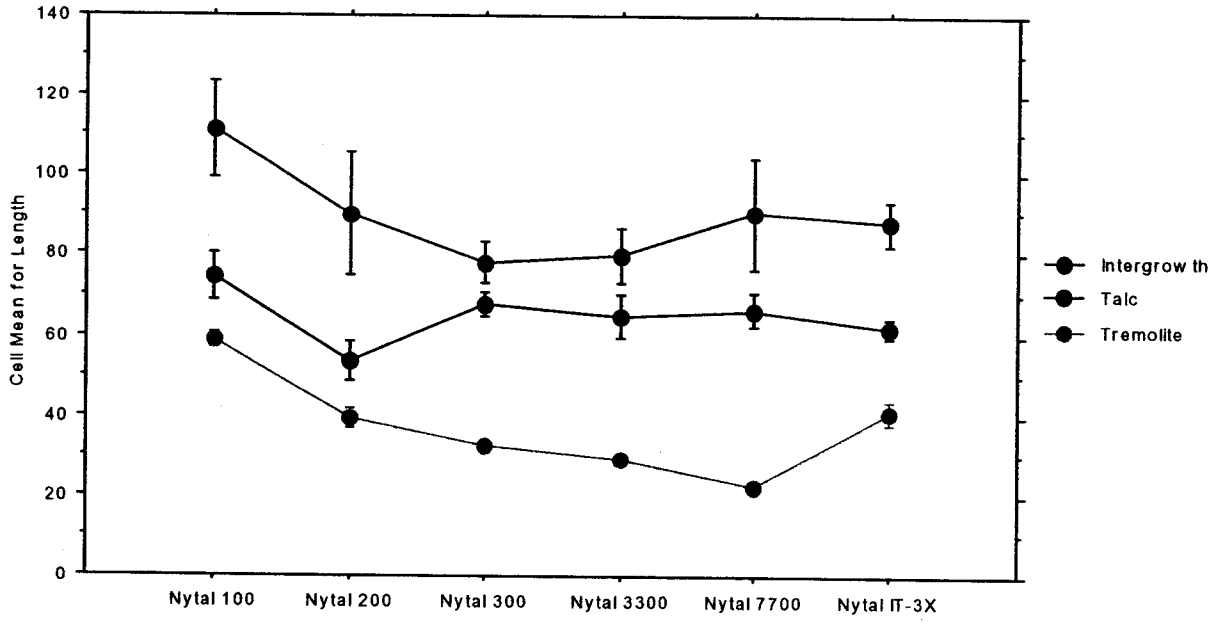


Figure 1. Comparison of particle length (µm) for Nytal products; all particles ≥ 3:1.

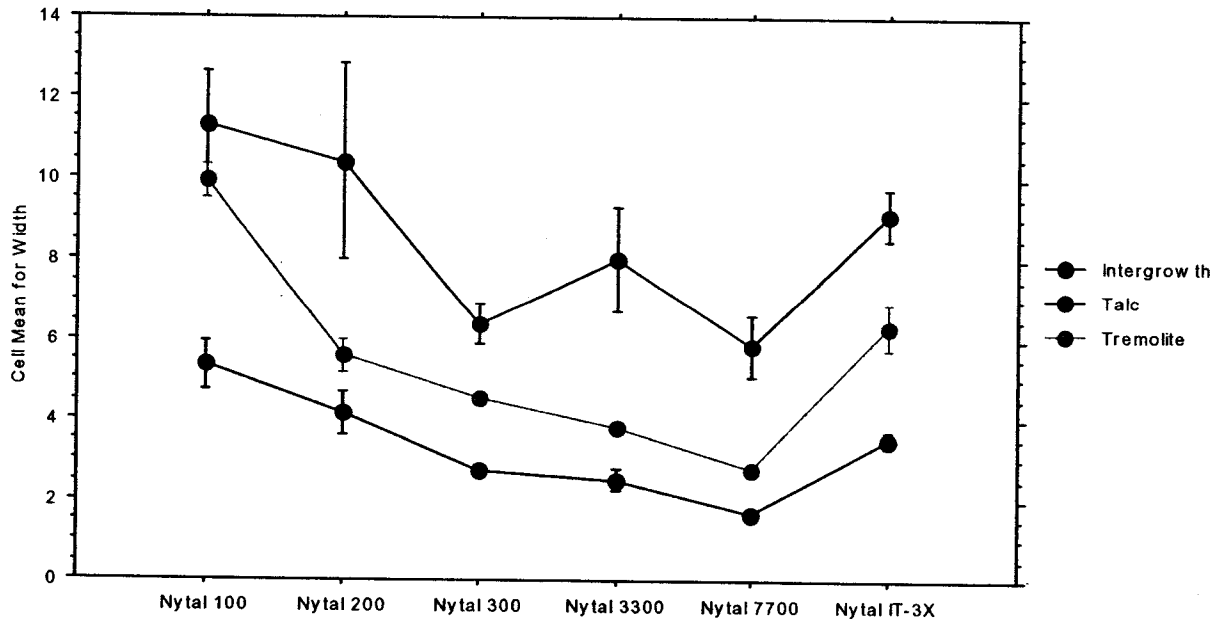


Figure 2. Comparison of particle width (µm) for Nytal products; all particles ≥ 3:1.

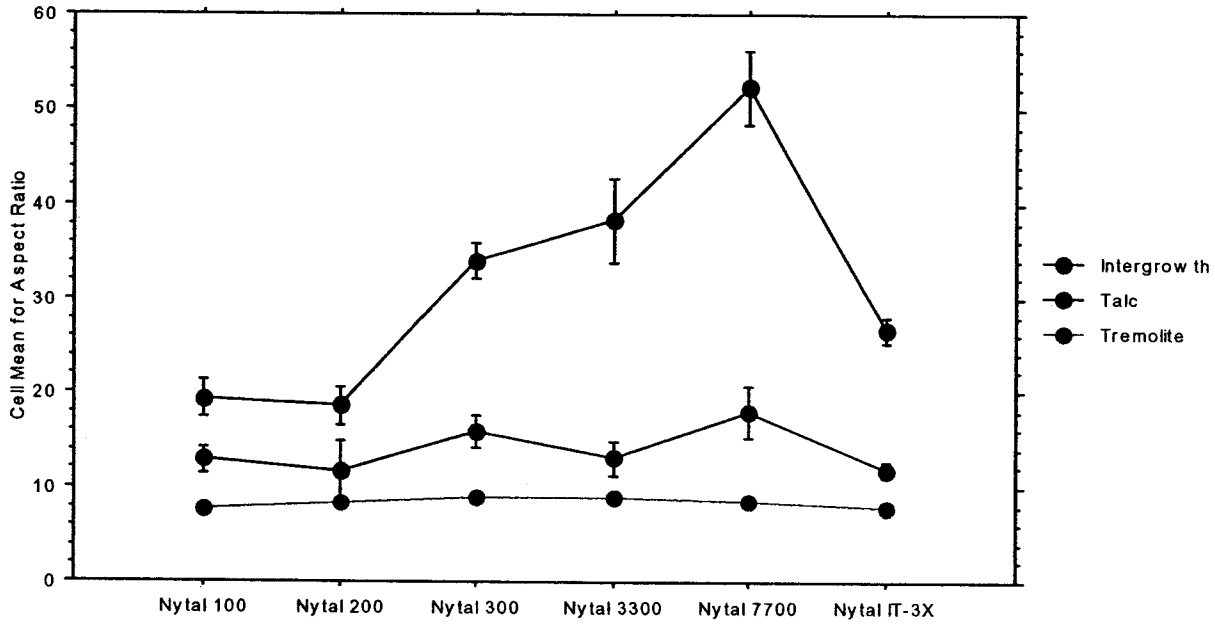


Figure 3. Comparison of Aspect Ratio for all particles ≥ 3:1 for Nytal products.

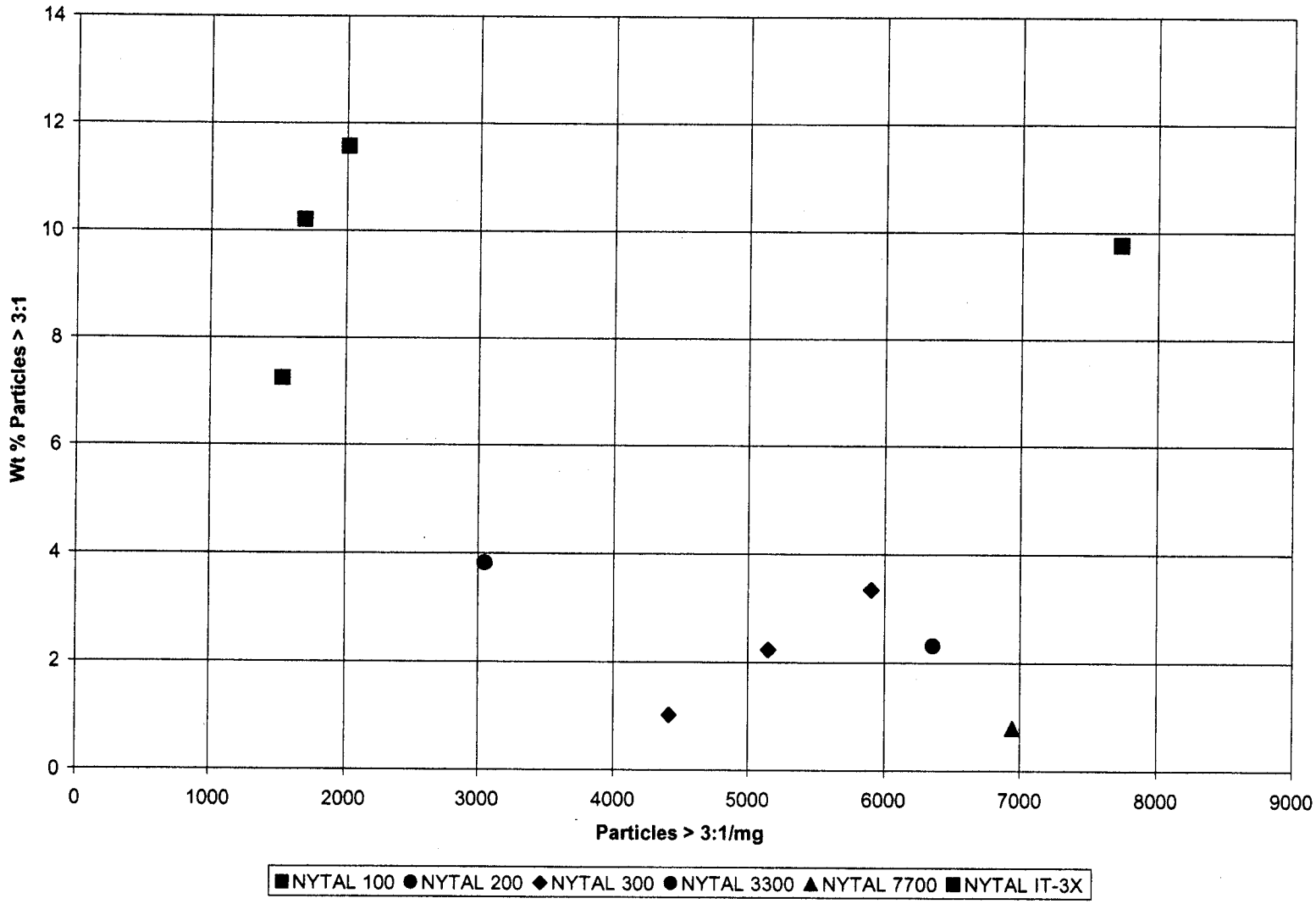


Figure 4. Comparison of particle number concentration and particle weight percent for NYTAL products.

ASBESTOS AND ASBESTIFORM DEFINITON/DESCRIPTION

A. ASBESTOS – A collective mineralogic term that describes a variety of certain silicates belonging to the serpentine and amphibole mineral groups, which have crystallized in the asbestiform habit causing them to be easily separated into long, thin, flexible, strong fibers when crushed or processed. Included in the definition are: chrysotile, crocidolite, asbestiform grunerite (amosite), anthophyllite asbestos, tremolite asbestos and actinolite asbestos.

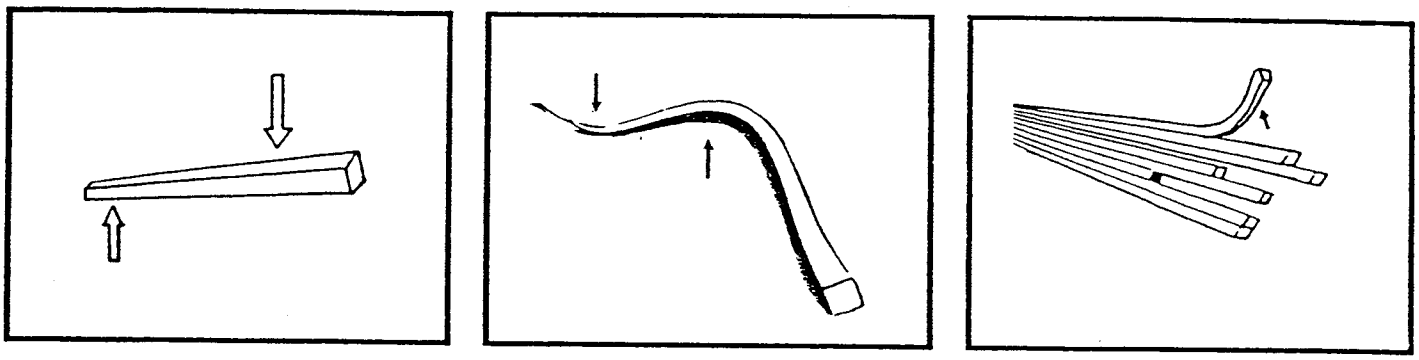
B. ASBESTOS FIBERS – Asbestiform mineral fiber populations generally have the following characteristics when viewed by light microscopy:

1. Many particles with aspect ratios ranging from 20:1 to 100:1 or higher for particles >5 um in length.
2. Very thin fibrils generally ≤ 0.5 micrometers in width.
3. In addition to the mandatory fibrillar crystal growth, two or more of the following attributes:
   (a) Parallel fibers occurring in bundles
   (b) Fibers displaying splayed ends
   (c) Matted masses of individual fibers
   (d) Fibers showing curvature

This definition represents the consensus of a group of mineral scientists, several of whom have published extensively in this area. (see Appendix I)

NOTE: The nomenclature and composition of amphibole minerals should conform with International Mineralogical Association recommendations (Leake, B. E., *Nomenclature of Amphiboles.* American Mineralogist. Vol. 63, 1023-1052. 1978).

ASBESTIFORM



In the asbestiform habit, mineral crystals grow in a single dimension along a parallel plane until they form long, thread-like fibers with aspect ratios of 20:1 to 100:1 and higher. When pressure is applied, the fibers do not shatter but simply bend much like a wire. "Fibrils" of a smaller diameter are produced as bundles of fibers are pulled apart (widths often <0.25 um). This bundling effect is referred to as "polyfilamentous." This should be viewed as the single most important characteristic as it is unique to asbestiform mineral growth.

ASBESTIFORM VARIETY
(Asbestos, CAS No. 1332-21-4*)

SERPENTINE GROUP

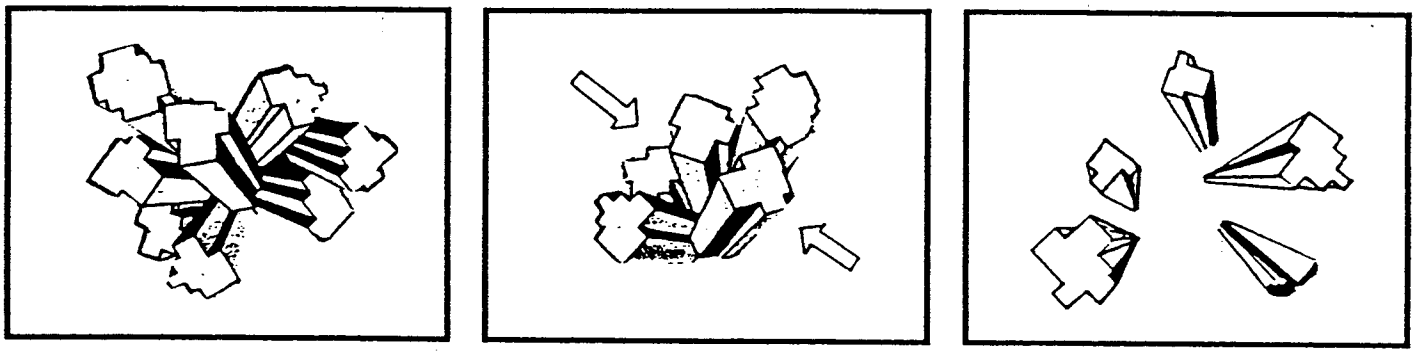
chrysotile	(CAS No. 12001-29-5)

AMPHIBOLE GROUP

crocidolite	(CAS No. 12001-28-4)
grunerite asbestos (amosite)	(CAS No. 12172-73-5*)
anthophyllite asbestos	(CAS No. 77536-67-5*)
tremolite asbestos	(CAS No. 77536-68-6*)
actinolite asbestos	(CAS No. 77536-66-4*)

The presence of an asterisk (*) following a CAS Registry Number indicates that the registration is for a substance which CAS does not treat in its regular CA index processing as a unique chemical entity.

NONASBESTIFORM



In the nonasbestiform variety, mineral crystal growth is random, forming multi-directional growth patterns. When pressure is applied, the crystals fracture easily, fragmenting into prismatic particles called cleavage fragments. Some particles or cleavage fragments are acicular or needle shaped as a result of the tendency of amphibole minerals to cleave along two dimensions but not along the third. Stair-step cleavage along the edges of some particles is common. Comminution of nonasbestiform rock produces a dust of large particulates with broad diameters (>0.25 um) and a relatively low particle number per unit mass of dust.

NON-ASBESTIFORM VARIETY

SERPENTINE GROUP

antigorite	(CAS No. 12135-86-3)

AMPHIBOLE GROUP

riebeckite	(CAS No. 17787-87-0)
grunerite	(CAS No. 14567-61-4)
anthophyllite	(CAS No. 17068-78-9)
tremolite	(CAS No. 14567-73-8)
actinolite	(CAS No. 13768-00-8)

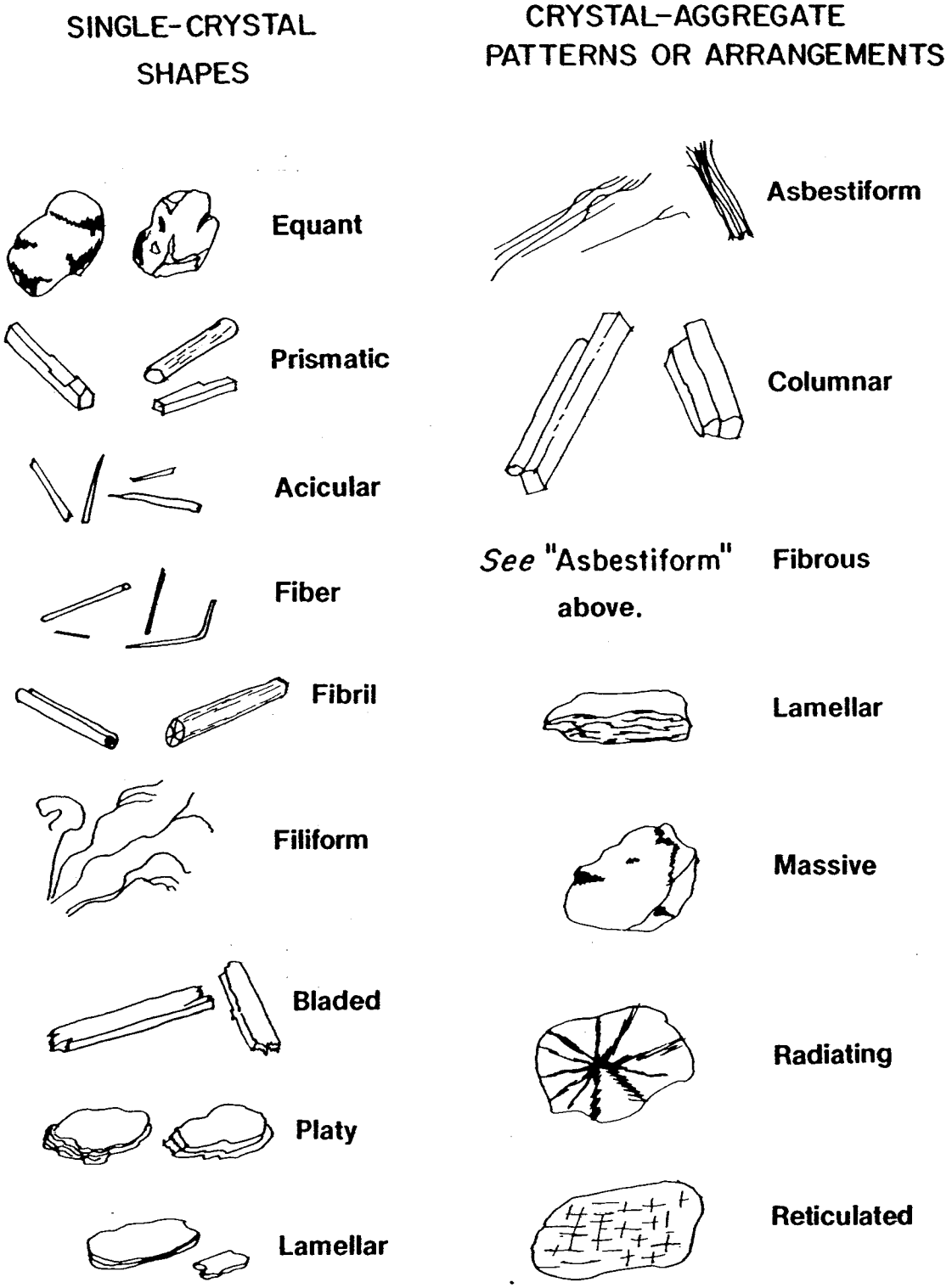
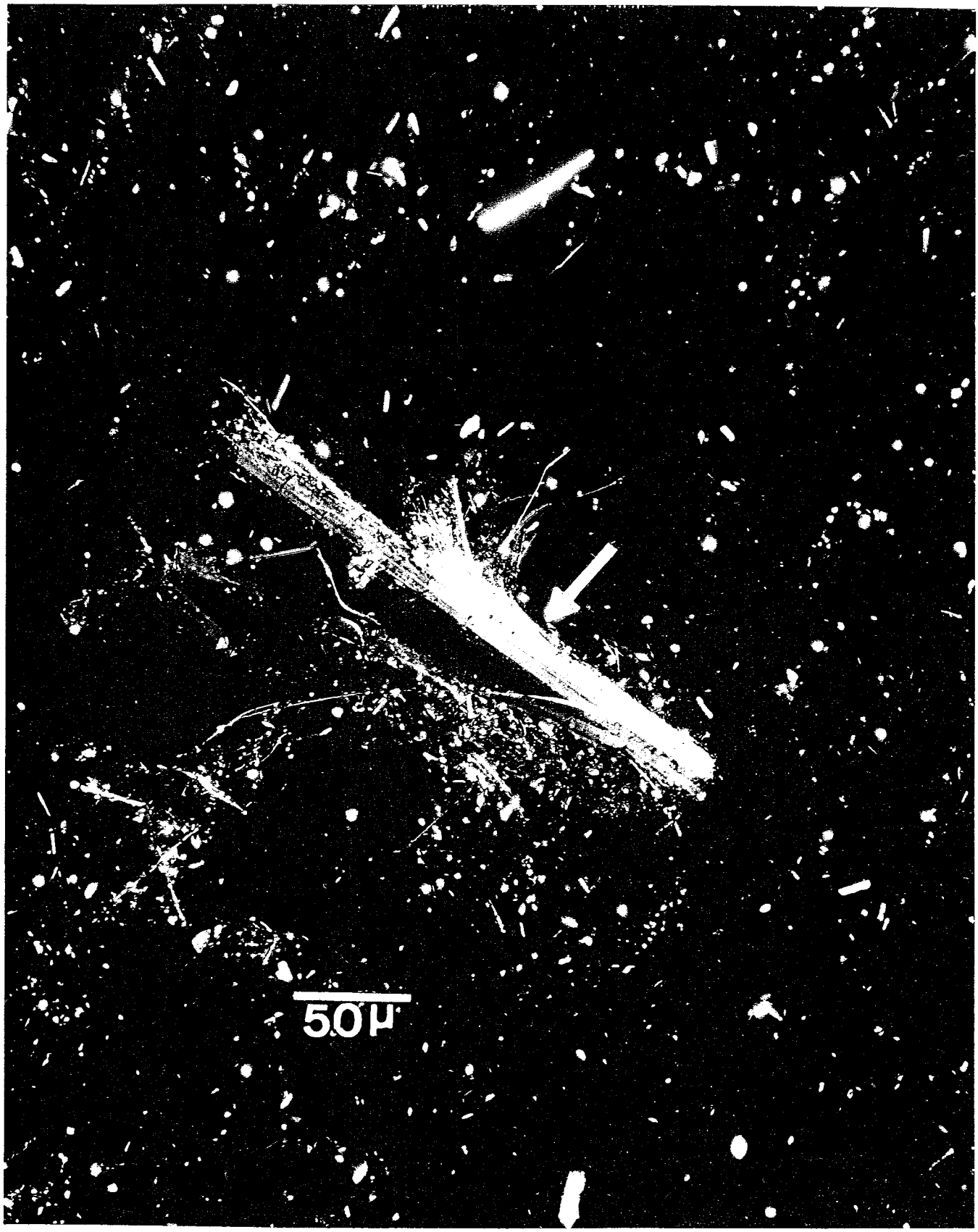


FIGURE 21. - Various shapes of single crystals, and patterns or arrangements of crystal aggregates.

EXAMPLES OF ASBESTOS FIBER



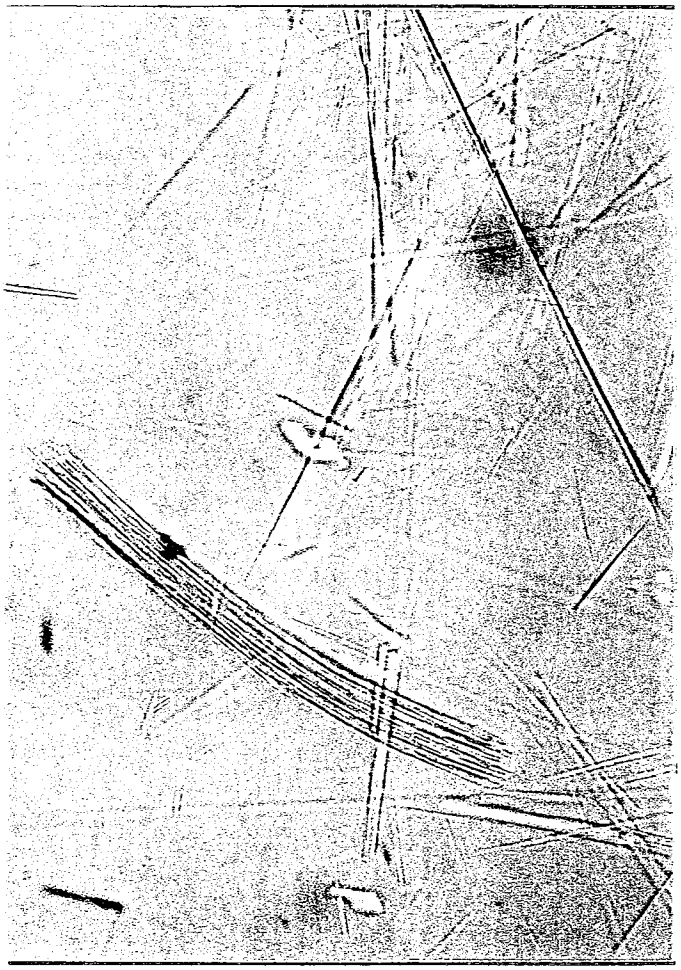
CHRYSOTILE BUNDLE

F1502 1000X

EXPOSURE EXHIBIT E ADDISON/DAVIS-TREMOLITE (Swansea)

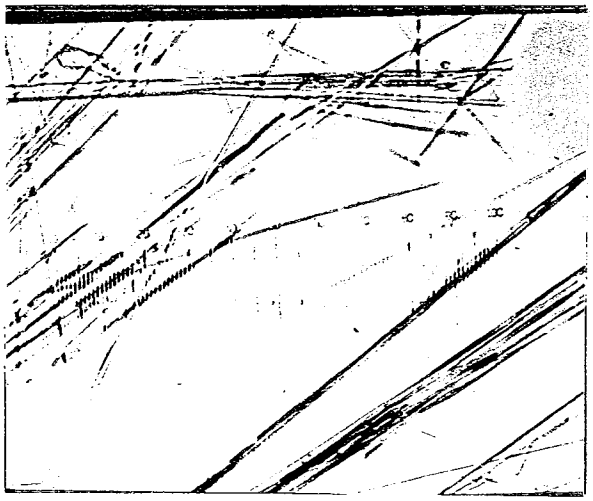
ASBESTIFORM TREMOLITE - ANIMAL STUDY

Light Microscopy: 320 X



SEM: 1.9 kX

REFERENCE
Light Microscopy



(2.75 um/division)
tremolite asbestos

SAMPLE: "Fine white tremolite asbestos, Swansea Laboratory." (Ref. 20) (Above photomicrographs were taken from bulk material.)

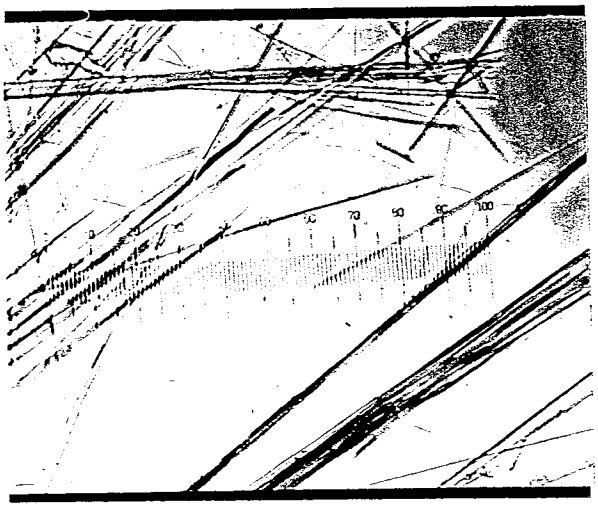
EXPOSURE EXHIBIT A — LIBBY MONTANA VERMICULITE

ASBESTIFORM TREMOLITE – HUMAN MORTALITY STUDY

Light Microscopy: 320 X

SEM: 1.18 kX

REFERENCE
Light Microscopy



(2.75 um/division)
tremolite asbestos

ORE: "The vermiculite ore as fed to the mill contained 4-6% amphibole fiber in the tremolite series." (13)

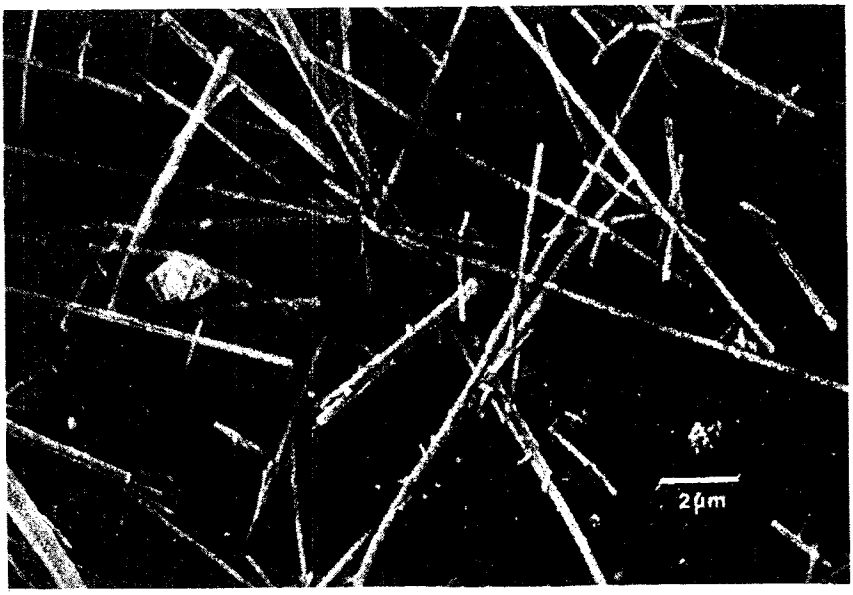


FIGURE A-6. - SEM photomicrograph of crocidolite fibers.

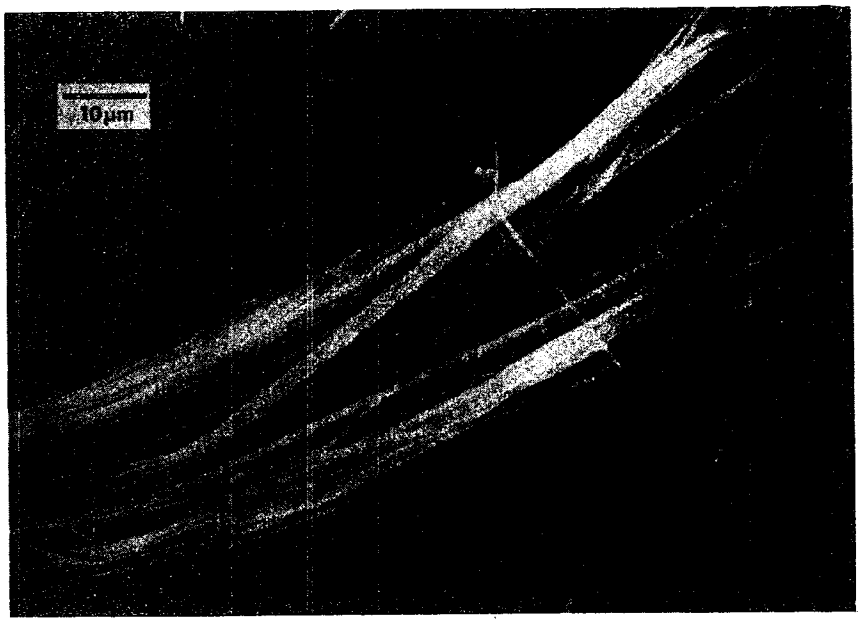


FIGURE A-7. - SEM photomicrograph of crocidolite fiber bundle.

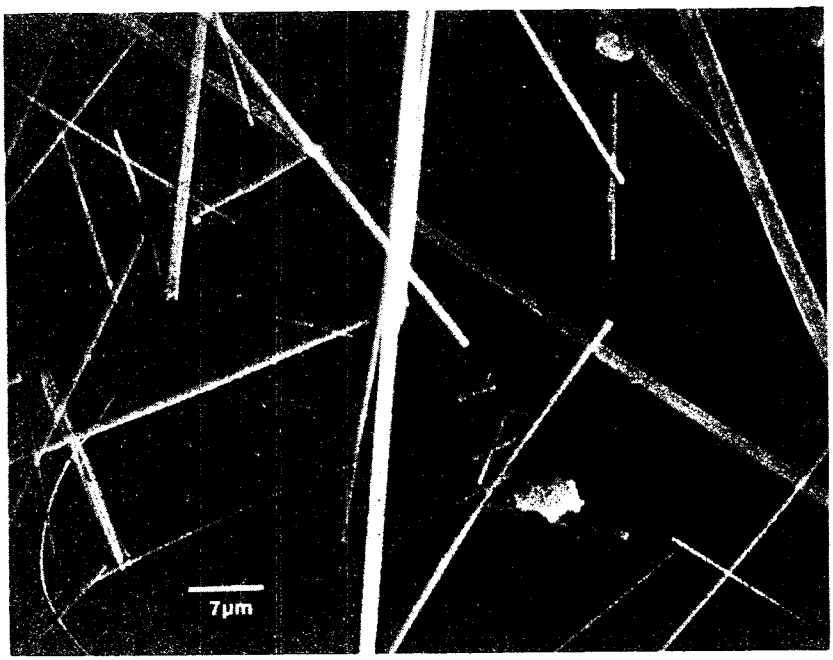


FIGURE A-2. - SEM photomicrograph of amosite fibers.

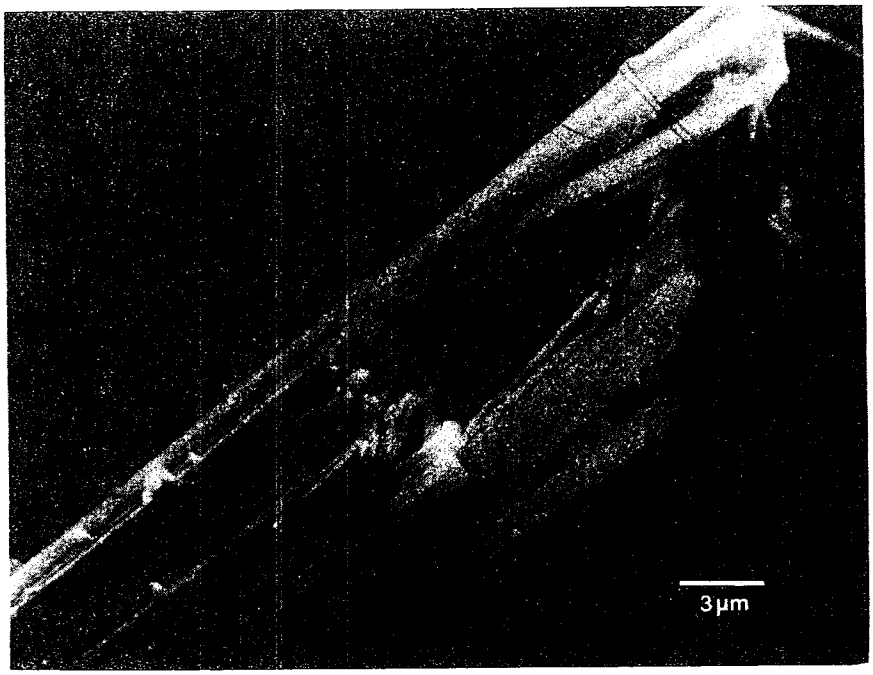


FIGURE A-3. - SEM photomicrograph of amosite fiber bundle.

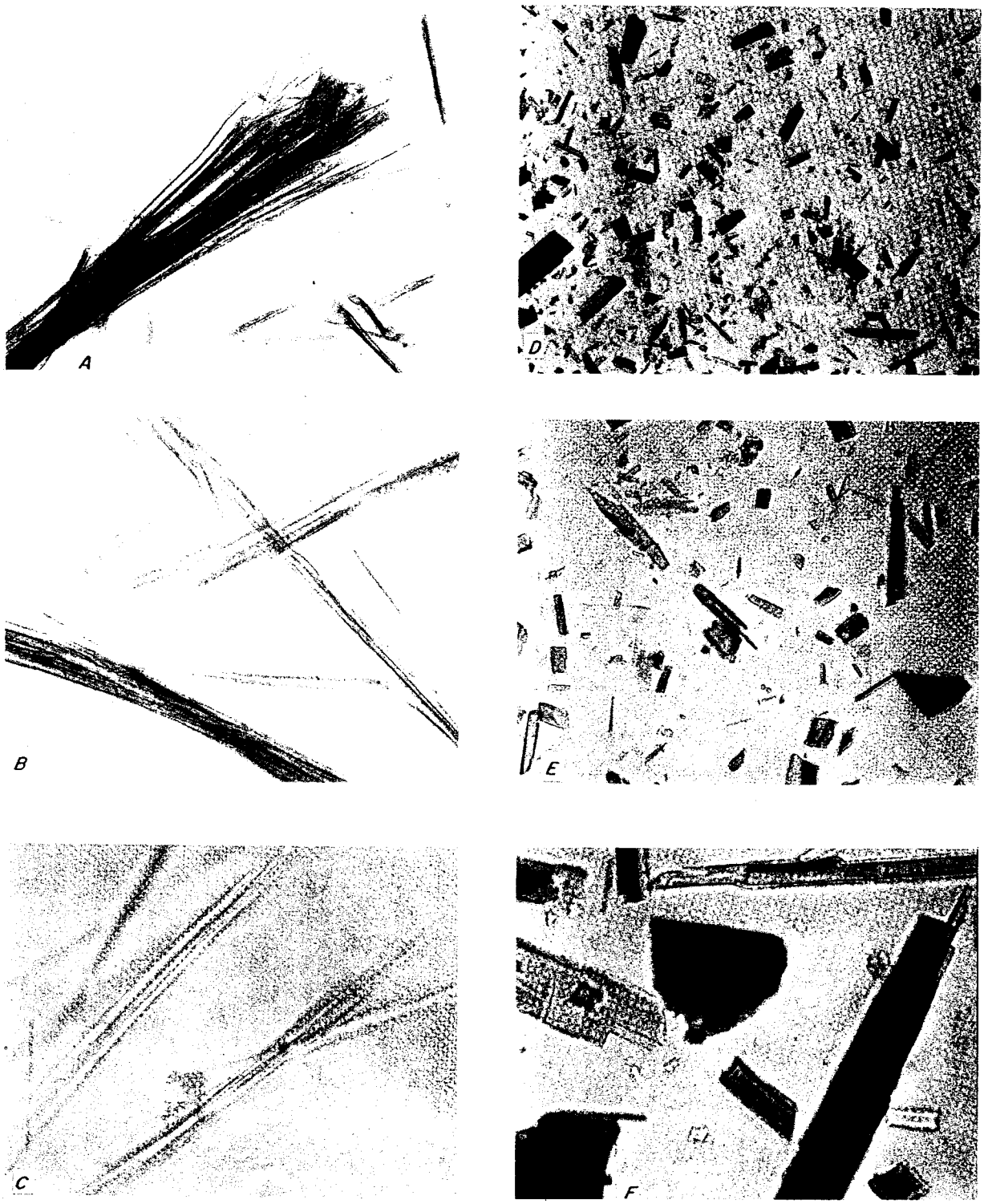


FIGURE 38. - Light optical photomicrographs of crocidolite and riebeckite at three magnifications; Crocidolite (left) at *A*, X 100; *B*, X 500; and *C*, X 950. Riebeckite (right) at *D*, X 100; *E*, X 500; and *F*, X 950.

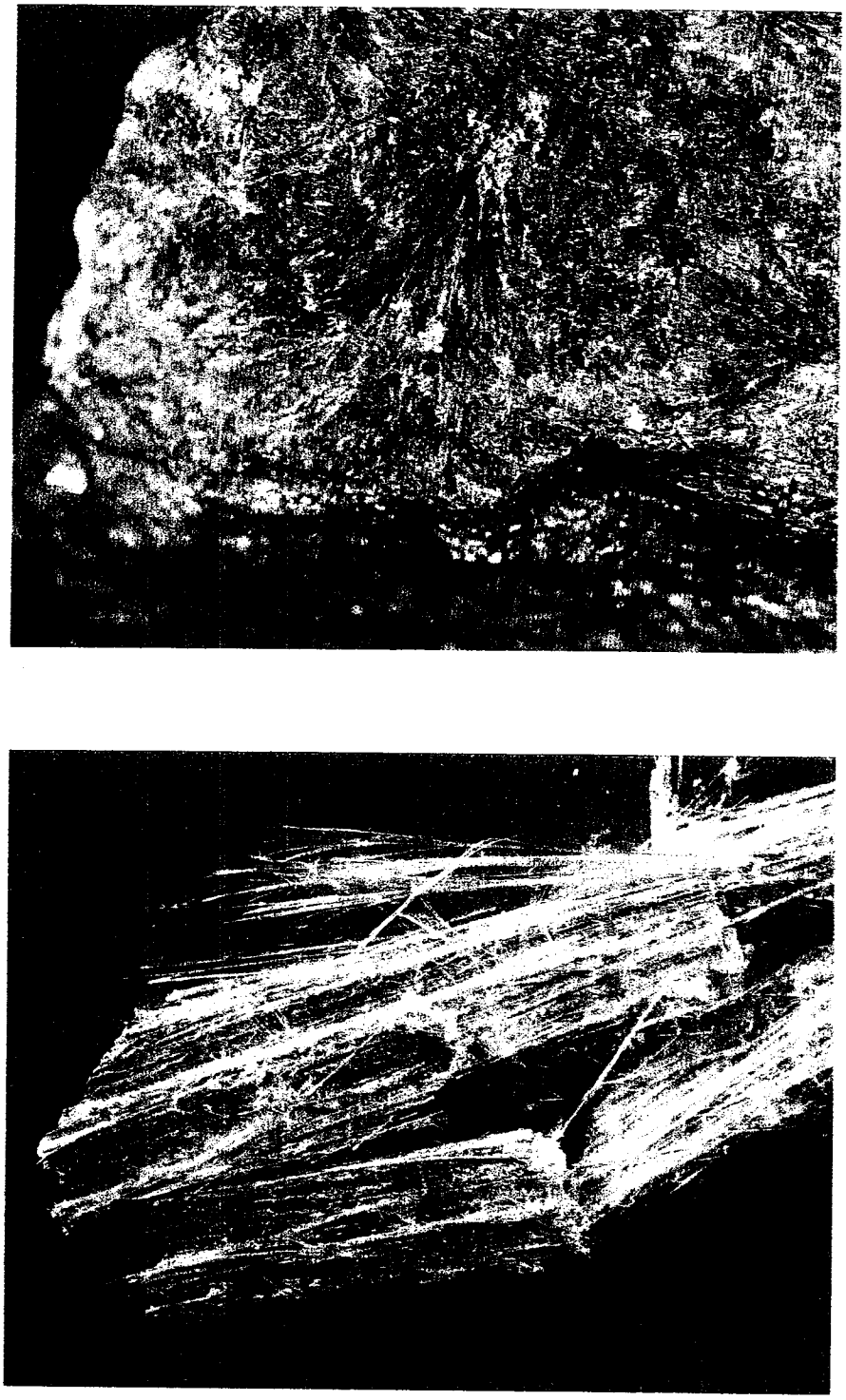


FIGURE 4. - Macrophotographs (X 3) of anthophyllite (top) and anthophyllite asbestos (bottom).

EXAMPLES OF TALC FIBER
AND MIXED
TALC-AMPHIBOLE FIBER IN VANDERBILT TALC

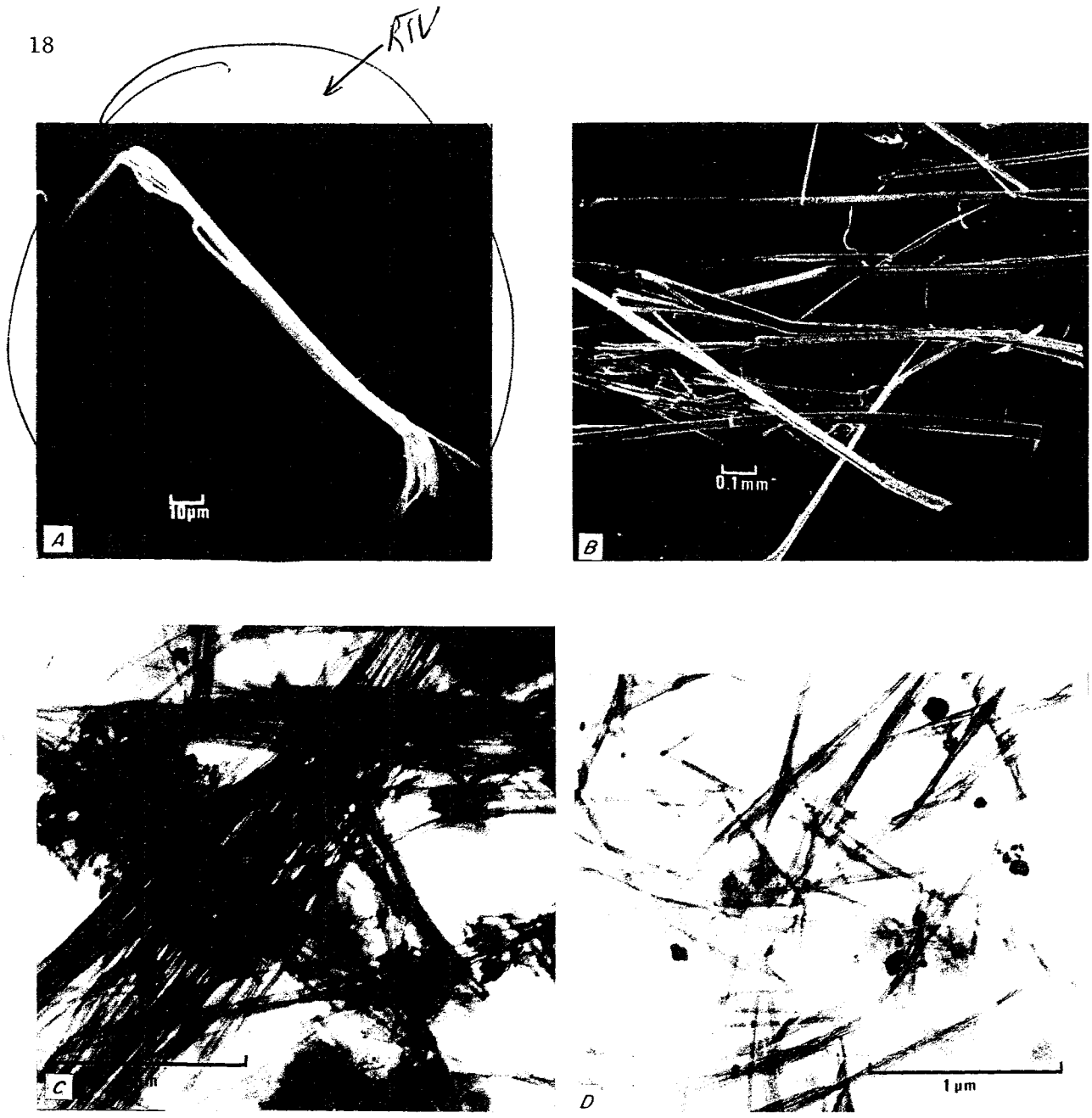


FIGURE 13. - Four fibrous nonasbestiform mineral varieties: *A*, Fibrous talc (X 500); *B*, fibrous brucite (X 50); *C*, palygorskite (X 30,000); and *D*, attapulgite (X 30,000).

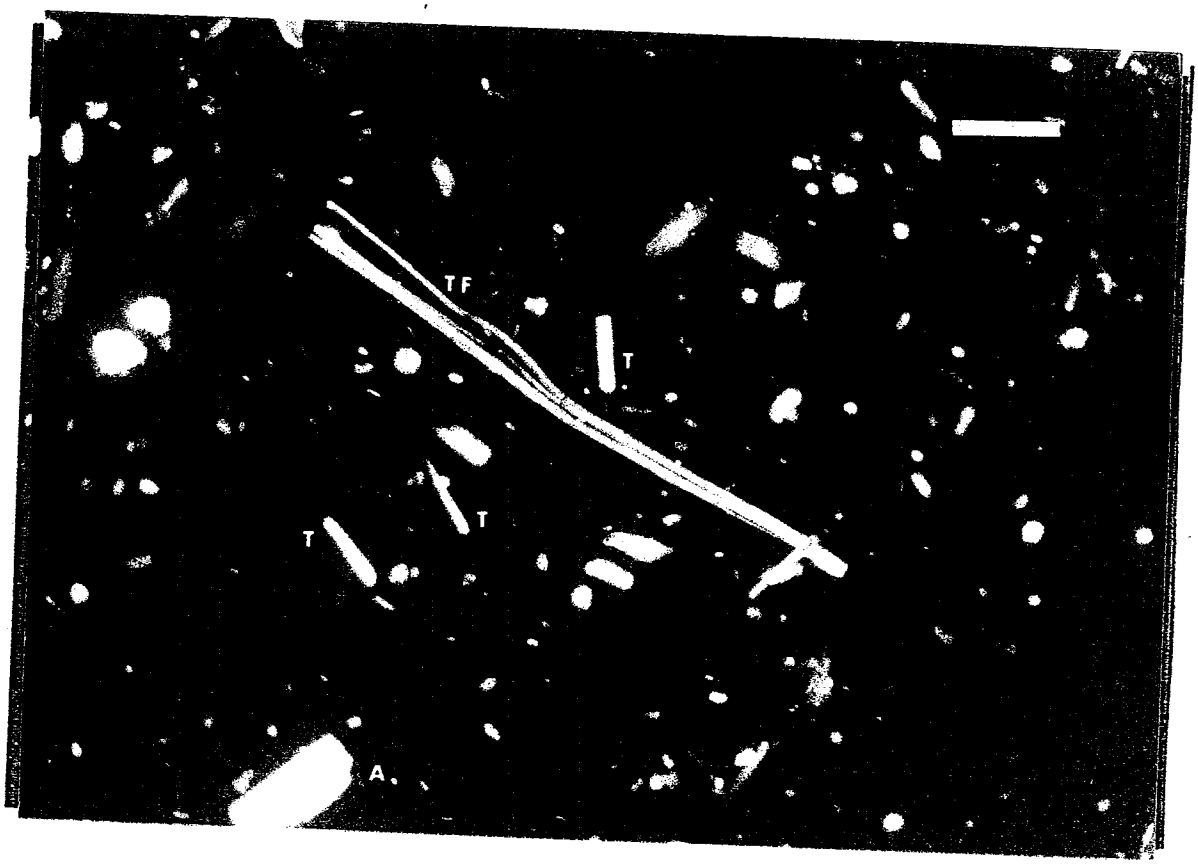
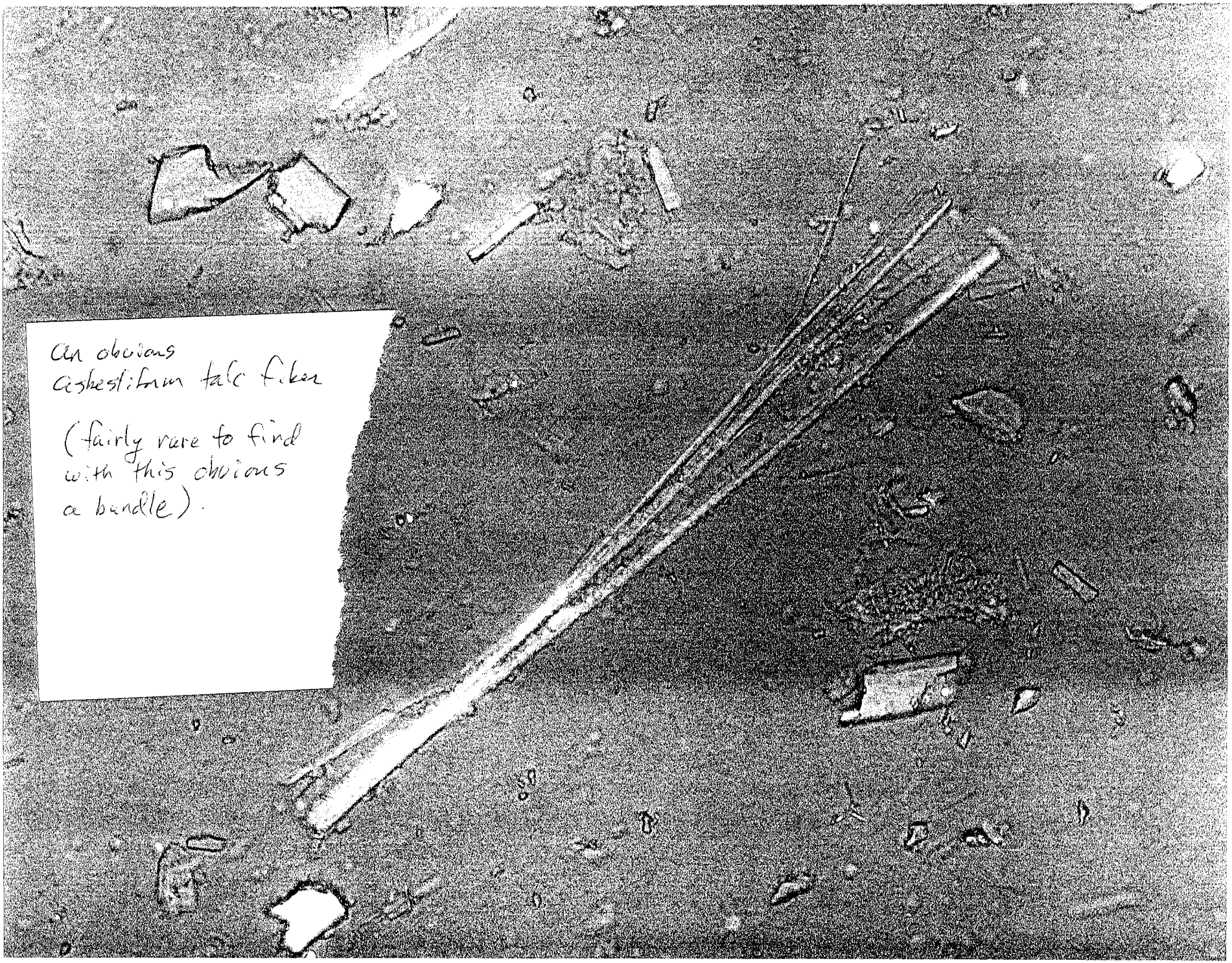


Figure 3. A typical asbestiform Type I talc fiber is labeled "TF". Tremolite cleavage fragments are labeled "T". The particle in the lower left labeled "A" is a prismatic anthophyllite cleavage fragment. The asbestiform habit contrasts sharply with that of the prismatic cleavage fragments. The length of the bar is 30 microns.


An obvious
asbestiform talc fiber
(fairly rare to find
with this obvious
a bundle).

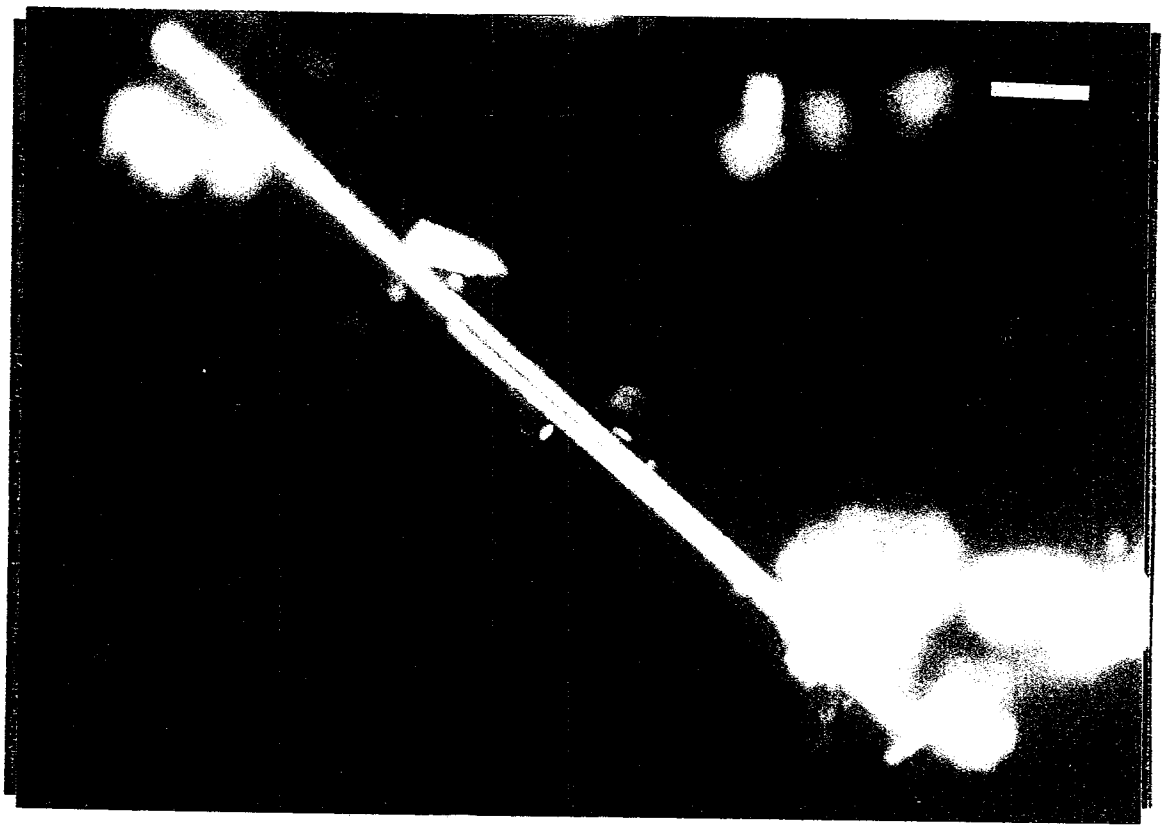


Figure 5. A Type II fibrous talc particle. At 90° to this, the ribbon-like habit of these fibers would be evident. The length of the bar is 10 microns.

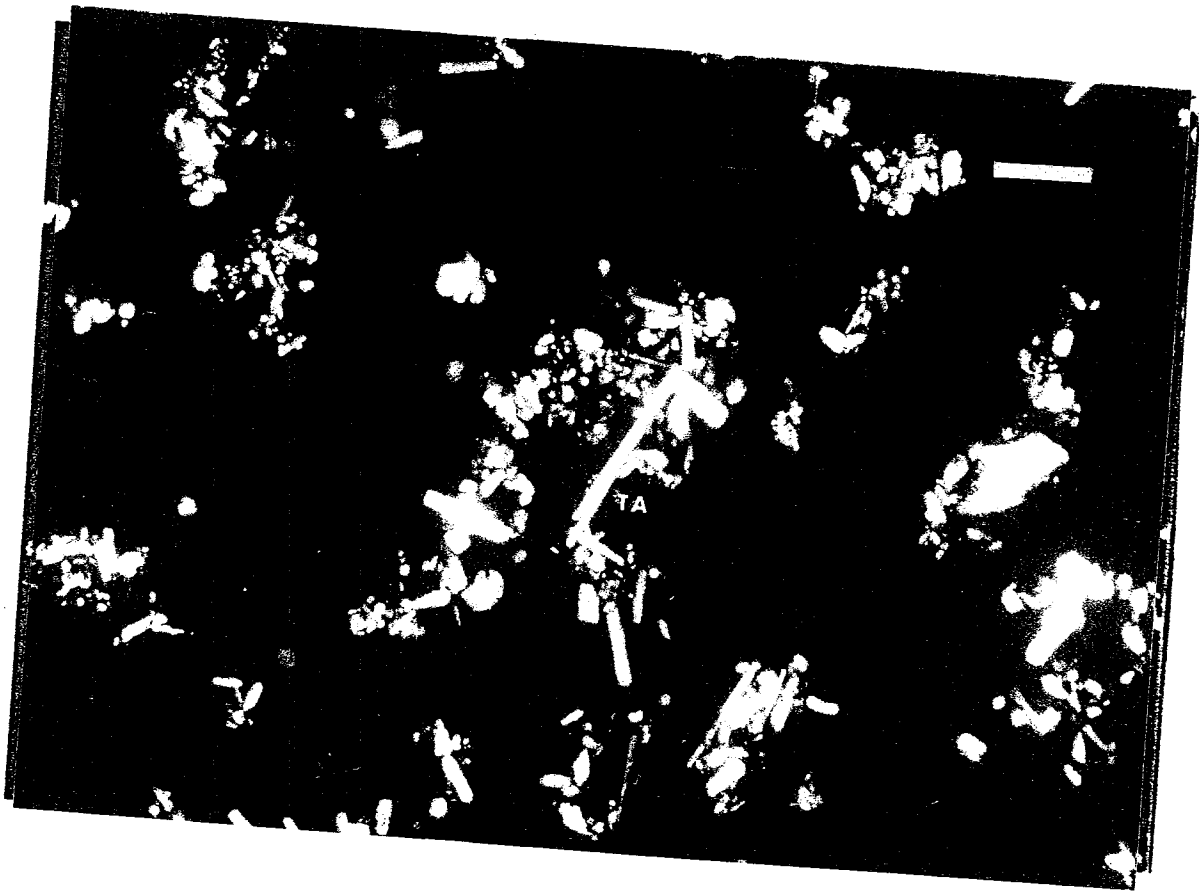


Figure 8. A talc-amphibole particle is labeled "TA". Note the resemblance to the talc shown in Figure 5. This particle was designated as talc-amphibole because γ was measured as 1.604. The length of the bar is 45 microns.

Figure 1. Example of talc intergrowth fiber.

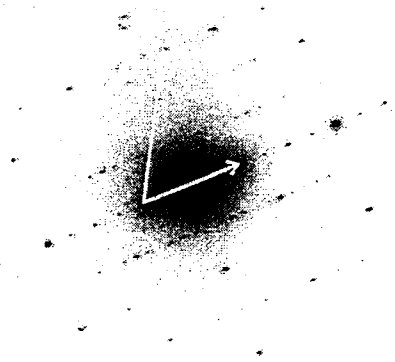


Figure 2. Selected area diffraction pattern of talc intergrowth fiber. Arrows mark measured dimensions. The circle encompasses representative intergrowth "triplet" spots.

c minerals

.n addition to the four minerals described above, serpentine, platy , and calcite were observed in the samples. None of the serpentine chrysotile. All of it has a platy habit; it is probably antigorite. Cargille immersion oil n_D = 1.556, it can be seen that the indices of efraction of the serpentine particles are close to the indices of refraction of this oil. None of the elongated mineral particles have an index of refraction parallel to elongation which is close to 1.556. For all the elongated minerals, the index of refraction which is parallel to the direction of elongation is greater than 1.556. Perpendicular to the direction of elongation, all amphibole particles have indices of refraction much greater than 1.556. Only fibrous talc may have α equal to 1.556. Still, fibrous talc should not be confused with chrysotile because fibrous talc has a high birefringence and a much larger γ.

CONCLUSIONS

Samples IT-IF and IT-325 are composed of essentially the same minerals. Four of these are elongated. Type I fibrous talc is clearly asbestiform. The talc-amphibole and fibrous talc Type II form acicular particles and there is evidence to suggest that they are marginally asbestiform. However, fiber bundles are rare and many of the particles may simply be acicular cleavage fragments like those shown in Figure 4. The anthophyllite is both acicular and prismatic, and the particles may be formed by growth or cleavage or both. However, the anthophyllite does not appear to be asbestiform. The tremolite particles are prismatic and blocky and are probably formed by cleavage alone. They are the most common elongated mineral particles in these samples. Type I fibrous talc and tremolite are readily distinguished from the other elongated minerals by their distinct habits. Type II fibrous talc, talc-amphibole and anthophyllite require precise determination of index of refraction data to make a positive identification. In fact, there is an apparent continuum between fibrous talc and anthophyllite in optical properties and habit. A similar series of minerals is present in anthophyllite-asbestos from Finland (UICC). There, however, fibrous talc is a minor constituent while anthophyllite is abundant. Here, fibrous talc is the common phase while talc-amphibole and anthophyllite occur in minor amounts.

Ann G. Wylie
Associate Professor

federal register

Monday
June 8, 1992

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926

Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926

[Docket No. H-033-d]

Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: In this final standard the Occupational Safety and Health Administration (OSHA) amends its present standards for regulating occupational exposure to asbestos in general industry (29 CFR 1910.1001) and construction (29 CFR 1928.56).

OSHA has reviewed available relevant evidence concerning the health effects of nonasbestiform tremolite, anthophyllite and actinolite and has also examined the feasibility of various regulatory options. Based on the entire rulemaking record before it, OSHA has made a determination that substantial evidence is lacking to conclude that nonasbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effect as asbestos. Further, substantial evidence does not support a finding that exposed employees would be at a significant risk because nonasbestiform tremolite, anthophyllite or actinolite was not regulated in the asbestos standards.

OSHA hereby lifts the Administrative Stay, removes and reserves 29 CFR 1910.1101, and amends the revised asbestos standards to remove nonasbestiform tremolite, anthophyllite and actinolite from their scope.

DATES: *Effective date:* This final rule shall become effective May 29, 1992.

Administrative stay: The Administrative Stay expired May 30, 1992.

ADDRESSES: For additional copies of this document, contact OSHA Office of Publications; U.S. Department of Labor, room N-3101, 200 Constitution Ave., NW., Washington, DC 20210, Telephone (202)-523-9667.

For copies of materials in the docket, contact: OSHA Docket Office, Docket No. H-033d, U.S. Department of Labor, room N-2625, 200 Constitution Ave., NW., Washington, DC 20210, Telephone (202)-523-7894. The hours of operation of the Docket Office are 10 a.m. until 4 p.m.

In compliance with 28 U.S.C. 2112(a), the Agency designates for receipt of petitions for review of this final decision, under section 6(f) of the OSH Act, the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, room S-4004, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: James F. Foster, Director of Information and Consumer Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, room N-3649, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Pertinent Legal Authority
III. Regulatory History
IV. Mineralogical Considerations
V. Health Effects
VI. Other Regulatory Issues
VII. Summary and Explanation of the Amendments
VIII. Authority

I. Introduction

This preamble discusses OSHA's decision to remove nonasbestiform tremolite, anthophyllite, and actinolite (herein referred to as ATA and/or nonasbestiform ATA) from the asbestos standards for general industry and construction (29 CFR 1910.1001 and 1926.58). Instead, exposure to nonasbestiform ATA will be regulated by the particulates not otherwise regulated (PNOR) limit in Table Z-1-A of 1910.1000 [15 mg/m^3 (total dust); 5 mg/m^3 (respirable dust)]. Becuase nonasbestiform ATA is found in combination with other minerals, some of which are regulated by other exposure limits in Table Z-1-A, some employees exposed to nonasbestiform ATA will be protected by those exposure limits as well.

OSHA is also removing and reserving 29 CFR 1910.1101, which was designated "Asbestos" and which has been applied to nonasbestiform ATA during the administrative stay of the revised asbestos standards (29 CFR 1910.1001 and 29 CFR 1926.58). OSHA has determined that the 1972 asbestos standard, which had been redesignated 1910.1101, no longer applies to nonasbestiform ATA and thus, there is no current reason to continue to include it in the Code of Federal Regulations.

As discussed further in this preamble, OSHA's determination to remove nonasbestiform ATA from the scope of the asbestos standards, is based on the insufficiency of evidence to support determinations that their further inclusion would protect exposed employees from a risk of disease which was the equivalent in incidence and gravity to asbestos related disease, and that removing coverage would pose a significant risk to exposed employees.

The Agency also finds that the evidence is insufficient to regulate nonasbestiform ATA as presenting a significant health risk to employees other than as a physical irritant, without regard to its analogy to asbestos. Thus no separate standard is necessary at this time and the PNOR limit is appropriate.

In summary the basis for these findings is as follows. Asbestos and nonasbestiform ATA appear to be distinguishable mineral entities on a population basis, and in most instances on a particle basis. The characteristics which differentiate them generally appear to correspond to the properties which may dictate different biologic response. There are mechanistic data from experimental animals exposed to various durable minerals which support counting some particles of nonasbestiform ATA like all asbestos fibers. However, available toxicological and epidemiologic evidence related specifically to nonasbestiform ATA is negative or inconclusive on the issue. Also, in most cases, particles of nonasbestiform ATA appear to be a very small fraction of the dust population to which employees are exposed. Therefore, OSHA finds there is insufficient evidence to support regulating nonasbestiform ATA as presenting a risk similar in kind and extent to asbestos.

Regulating nonasbestiform ATA on its own is also precluded by the limitations of the available evidence. Dose response data concerning nonasbestiform ATA exposure alone is not available; human and animal studies concerning nonasbestiform ATA are individually and collectively, equivocal. Most of the studies do not, on their face report results which show a statistically significant positive response due to nonasbestiform ATA exposure. Criticisms concerning their interpretation mainly concern their power to disprove an association between nonasbestiform ATA exposure and abestos-related disease. OSHA finds that even if these criticisms are accepted, the totality of evidence still does not constitute affirmative evidence supporting regulating nonasbestiform ATA as presenting a significant health risk.

This rulemaking record therefore is distinguishable from the body of evidence in the EtO rulemaking which was considered "compelling" in the aggregate, although most of the studies were individually flawed. *(Public Citizen Health Research Group* v.

Tyson, 796 F2d 1479). Accordingly, the Agency has determined to not regulate nonasbestiform ATA exposure in a separate standard, since it is unable to conclude, given the information currently available, that it presents a significant risk to exposed employees, at current exposure levels, at any of the asbestos PELs which applied during the history of asbestos standards, or at any other specific level.

OSHA also believes that evidence in this record does not show that removing nonasbestiform ATA from the scope of the asbestos standards will pose a significant risk to exposed employees. As discussed later in this document, testimony and evidence which is not controverted, indicates that, although there is a risk of nonmalignant respiratory disease from high exposures to talc containing nonasbestiform ATA, (See discussion during regulatory alternatives), nonasbestiform ATA is not identified as the causative agent of such nonmalignant disease. OSHA has also determined that there is insufficient health effects evidence linking exposure to nonasbestiform ATA to a heightened risk of cancer. Historic exposure levels of talc containing nonasbestiform ATA (converted from mppcf) linked to production of excess nonmalignant disease have been estimated as approximately 4 to 12 mg/m ^{3}. At levels estimated at approximately 1.5 to 6.5 mg/m ^{3} (Ex. 84–141, docket H–033c, Kleinfeld et al., at 665; conversion made by ACGIH 1986) excess nonmalignant respiratory disease appears to be eliminated. The current PEL for talc is 2 mg/m ^{3}. (Talc is measured on a gravimetric basis rather than by fiber and is thus measured in mg/m ^{3}.)

Without inclusion in the asbestos standards, employees exposed to nonasbestiform ATA will be covered by various dust limits in OSHA's Air Contaminant Standards (29 CFR 1910.1000 and 29 CFR 1926.55). Those employees exposed to tremolitic talc, will be covered by the talc standard as well, for that fraction of their exposure which constitutes talc. Where exposure occurs to a mixture of substances the mixture formula in the Air Contaminant Standard applies. Therefore workers exposed to nonasbestiform ATA contaminated talc, the commercial product most likely to contain sizable amounts of nonasbestiform ATA, will be protected by several permissible exposure limits and hazard communication provisions.

The other industries where nonasbestiform ATA exposure occur are those where ATA are constituents of crushed rock and stone. At the time of the proposal, OSHA's contractor reported the following conclusions about the potential for exposure to nonasbestiform ATA in industries which consume crushed stone, sand, and gravel. "The occurrence of nonasbestiform tremolite, actinolite, and/or anthophyllite is erratic and unpredictable. However, when it does occur—even in significant quantities—it does not appear that construction or other activities which disrupt the minerals and produce dust result in airborne fiber levels which exceed OSHA's action level 0.1 f/cc. "(CONSAD report, Ex. 465 at 1.14). (In this example, particles of nonasbestiform ATA, which are greater than 5 microns in length and have aspect ratios greater than or equal to 3:1, are measured as "fibers/cc" as opposed to the example above where dust was measured on a gravimetric basis.)

No evidence was presented in the rulemaking which showed that workers will be exposed to airborne levels of nonasbestiform ATA during activities involving crushed rock or stone which significantly exceed CONSAD's estimate. Therefore, OSHA concludes that removing these workers from the protection of the asbestos standard will not result in a significant health risk to them because, even if workers were exposed to levels estimated by OSHA's contractor, there would likely be no significant risk.

The Agency acknowledges that certain public health organizations have recommended that OSHA continue to regulate nonasbestiform ATA under the asbestos standards. Thus, the American Thoracic Society (ATS) concluded that "(a)t present, the prudent public health policy course is to regard appropriately sized (non-asbestiform) tremolite "fibers" in sufficient exposure dose (concentration and duration), as capable of producing the recognized asbestos-related diseases, and they should be regulated accordingly. (Ex. 525 at 15). As discussed in detail in the section on mineralogy, OSHA continues to believe that fiber dimension is the most significant indicator of fiber pathology. However, there is insufficient evidence in the record to determine the parameters of "appropriately sized" tremolite particles. In addition the evidence which is available most likely associates fibers with dimensions common to asbestos populations with disease causing potential than particles found in nonasbestiform ATA populations. For example, the Stanton index particle of at least 8 μm in length and less than .25 μm in width, is rarely associated with nonasbestiform ATA particles, but is a common dimension for asbestos fibers.

NIOSH also recommends that OSHA continue to regulate nonasbestiform ATA under the asbestos standards. Its major rationale is similar to the ATS's, i.e. "NIOSH concludes for regulatory purposes that cleavage fragments of the appropriate aspect ratio and length from the nonasbestiform minerals should be considered as hazardous as fibers from the asbestiform minerals." (Tr. 5/9, p. 9). As stated above, OSHA does not believe that the current record provides an evidentiary basis to determine "the appropriate aspect ratio and length," for determining pathogenicity. Even if dimensional cut-offs were known for asbestos fibers, additional data do not support a standard for all ATA minerals based on fiber dimension alone. Available data show that asbestos containing dusts have much greater potency than non-asbestos containing dusts. Nor is there direct evidence showing fiber equivalency for asbestos and nonasbestiform ATA. NIOSH's additional concern is that by deregulating nonasbestiform ATA, OSHA will leave unprotected workers who may be exposed to asbestos, as a contaminant of a nonasbestiform mineral deposit or product to which they are exposed. (See Tr. 5/9, pp. 10–14). In this regard OSHA notes that available evidence indicates that significant contamination of nonasbestiform mineral deposits is identifiable and thus amenable to regulations under applicable asbestos standards.

Thus, OSHA does not believe that potential asbestos contamination of nonasbestos minerals, including nonasbestiform ATA, is sufficient reason to include such nonasbestiform minerals in the asbestos standard. If the presence of asbestos is known, it should be evaluated for extent and exposure potential. The definition of asbestos in the asbestos standards, and the counting criteria therein are sufficiently broad so as to cover all identifiable asbestos fibers. As discussed later in this document, OSHA has not changed these provisions. If an identification error is made, it is likely to be a false positive for asbestos rather than a false negative. Airborne exposure data in the record relating to naturally occurring asbestos as a contaminant, show that exposure potential is likely to be very low, even where asbestos is a major contaminant. (CONSAD study, Ex. 465)

Also, answering NIOSH's concerns, evidence in the record shows that differential analysis of mineral deposits and products can and is being performed using a variety of methods.

ABSENCE OF LUNG CANCER RISK FROM EXPOSURE TO TREMOLITIC TALC

by:

Steven H. Lamm, M.D.

Full Report
Submitted with
original
submission to NTP

February 14, 1986

ABSENCE OF LUNG CANCER RISK FROM EXPOSURE TO TREMOLITIC TALC

Abstract:

Analysis of employee mortality and job exposures supports the hypothesis that New York State talc is non-carcinogenic in man, as well as in animals. Lung cancer rates for New York State tremolitic talc workers were no different than the rates for Vermont non-tremolitic talc workers. Lung cancer rates in each state were much greater for miners than millers, although exposures were greater for millers than for miners. Lung cancer risk was not attributable to the high exposure jobs in either the mine or the mill. Among New York State talc miners, risk decreased with duration of employment rather than increased. Lung cancer risk was greatest for those with minimal employment. Analysis of the work histories prior to employment at the New York State talc plant suggests that this higher risk for short term employees may be explained by their previous employment in hazardous (for lung cancer) jobs prior to their short employment at the talc plant. Further detailed analysis of the exposure histories of individual cases does not support the hypothesis that the constituents of tremolitic talc contribute an additional carcinogenic risk.

Key Words:

Lung Cancer, Tremolite, Talc, Lung Diseases, Risk, Pre-hire Risks, New York State, Epidemiology

worklife. The median proportion was 0.9 per cent. The results of this analysis weakens the strength of the hypothesis of GTC employment or exposure at GTC as the probable cause of the lung cancer.

Mortality Comparison with Vermont Talc Workers

However, data is available for testing the original NIOSH hypothesis that the tremolite and anthophyllite in the GTC talc were responsible for the increased lung cancer risk. NIOSH has previously conducted a cohort mortality study of miners and millers employed for at least one year in the Vermont talc industry which NIOSH published as a study of workers exposed to "non-asbestiform" talc (35). Roughly similar cohorts can be identified within the two studies. The Vermont study is restricted to male Caucasians employed in the Vermont talc industry for over one year within the thirty year period, 1940-69 and with mortality follow-up through 1975. A similar group within the GTC cohort are those male Caucasians employed in the GTC talc plant for at least one year (experienced workers) within the thirty year period, 1947-77, and with mortality follow-up through 1978. The Vermont study has separated out the analysis of miners and millers. The same can be done with the GTC study, as seen in Table 6.

Comparisons of the GTC and the Vermont data are demonstrated in Table 9 and Figures 1 and 2. Table 9 and Figure 1 give the lung cancer risks for experienced talc workers in Vermont State and in New York's GTC talc plant. The numbers for the miners and millers in the Vermont Study do not entirely add up to the total for a number of definitional reasons. The total group includes workers who were employed for over one year in the talc plant but with neither one year in the mine nor one year in the mill. Persons who worked in the mine and the mill are counted both for the miners and for the millers, but are counted only once in the total. There is one case in Vermont with over one year in the mine and more than one year in

the mill. Thus, he is in each of the three sub-tables, each of which demonstrates an equal or greater risk among experienced Vermont State talc workers than among experienced New York State (GTC) talc miners. The New York State data is separate out into those who worked in the mine but not the mill and those who worked in the mill but not the mine. There were no cancer or NNRD deaths among the New York state talc workers who worked both in the mine and the mill.

Although the comparison of data on New York State talc workers and Vermont State talc workers is presented as lung cancer, the New York data applies only to lung cancer (ICD 162.1) and the Vermont data applies to respiratory cancer (ICD 160-164). Both the Vermont State talc cohort and the GTC cohort had one death from mesothelioma, but in neither case was it attributed to talc exposure.

Table 9 and Figure 1 demonstrate no apparent difference in lung cancer risks in workers exposed to talcs containing tremolite and anthophyllite at the exposure levels historically found in this GTC plant and those exposed to talcs not containing these minerals. Whatever the nature of the particulates, their presence does not appear to cause an increased carcinogenic risk, such as that associated with asbestos.

This paper has limited itself to an assessment of evidence of a carcinogenic risk due to exposure to respirable anthophyllite and tremolite dust in GTC talc. Similarly, an assessment of non-carcinogenic respiratory mortality of the talc workers could be made. Such an analysis would show an increased non-infectious, non-neoplastic respiratory disease (NNRD) mortality risk that was greater in long-term workers than in short-term (<1 year) workers, and greater among those without known prior carcinogenic risk from employment than among those with known prior carcinogenic risk. The risk of miners seemed to be somewhat greater than that of millers at GTC, while, in Vermont State, the NNRD risk was markedly

greater in talc millers than in talc miners (Table 9 and Figure 2). These differences may reflect differences in airborne respirable dust levels in the different mines and mills, rather than differences in the mineralogic nature of the dust. Prior employment in other New York State talc mines was associated with an increased risk of NNRD among GTC employees but not of lung cancer.

Mortality Comparison with Amphibole Cleavage Exposure

Further, the results of this analysis are consistent with other epidemiologic studies with exposure to amphibole cleavage fragments. Higgins' study of Taconite workers found no association between taconite dust exposure and total mortality, cancer mortality, or respiratory cancer mortality (36).

McDonald's study of the Homestake gold miners with lung exposure to amphibole particles in the Cummingtonite-Grunerite series similarly demonstrated no association between exposure and lung cancer mortality (37), despite an earlier analysis by other authors suggesting significant malignant and non-malignant respiratory disease due to amphiboles characterized as "asbestiform mineral fibers" (38).

Health Findings among Talc Workers

It appears that exposure to dusts in the various studied talc mines and mills in the United States are generally associated with increased non-neoplastic pulmonary disease, but not with lung cancer. NIOSH has conducted mineralogic analyses and medical examinations at talc plants in Montana, Texas, and North Carolina, along with New York state (30). In each case, airborne dust levels were higher in the mill than in the mines. The elongated particulates seen in the New York State talc plant were not seen by light microscopy in the talcs of the other three states. While there is evidence that workers at GTC develop pulmonary fibrosis and bilateral pleural thickening, so do workers in other talc mines. NIOSH found "an elevated prevalence of pleural thickening in all

TABLE 9

Comparison of Mortality Risks of
Vermont State and New York State
Talc Workers Employed at Least 1 Year
(Expressed as SMR)

	Vermont		New York	
Cause of Death	O/E	SMR	O/E	SMR
All deaths	44/37.15	118	63/49.8	126
Lung Cancer	6/3.69	163	5/3.0	161
NNRD	11/1.79	615*	6/1.6	372*
Lung Cancer				
Millers	2/1.96	102	1/1.4	71
Miners	5/1.15	435*	4/1.1	368*
NNRD				
Millers	7/0.89	787*	2/0.7	270
Miners	2/0.56	357	2/0.5	408

* $p < 0.05$., two-tailed test

Figure 1

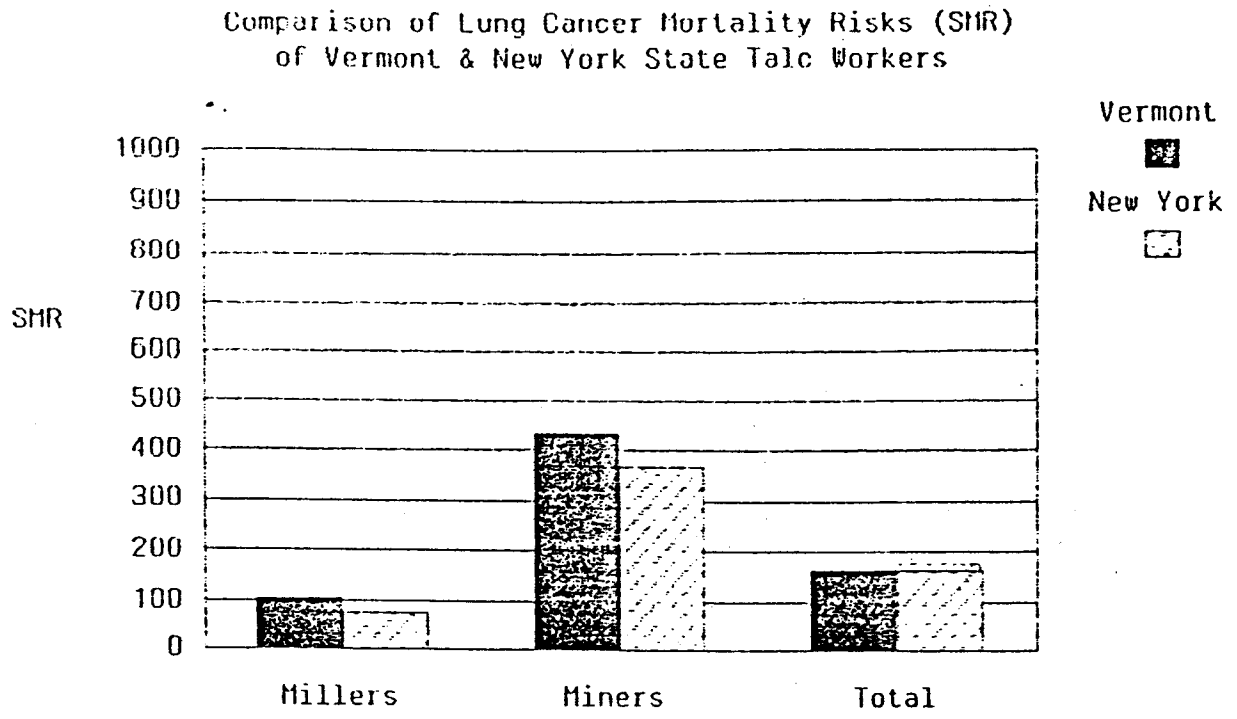
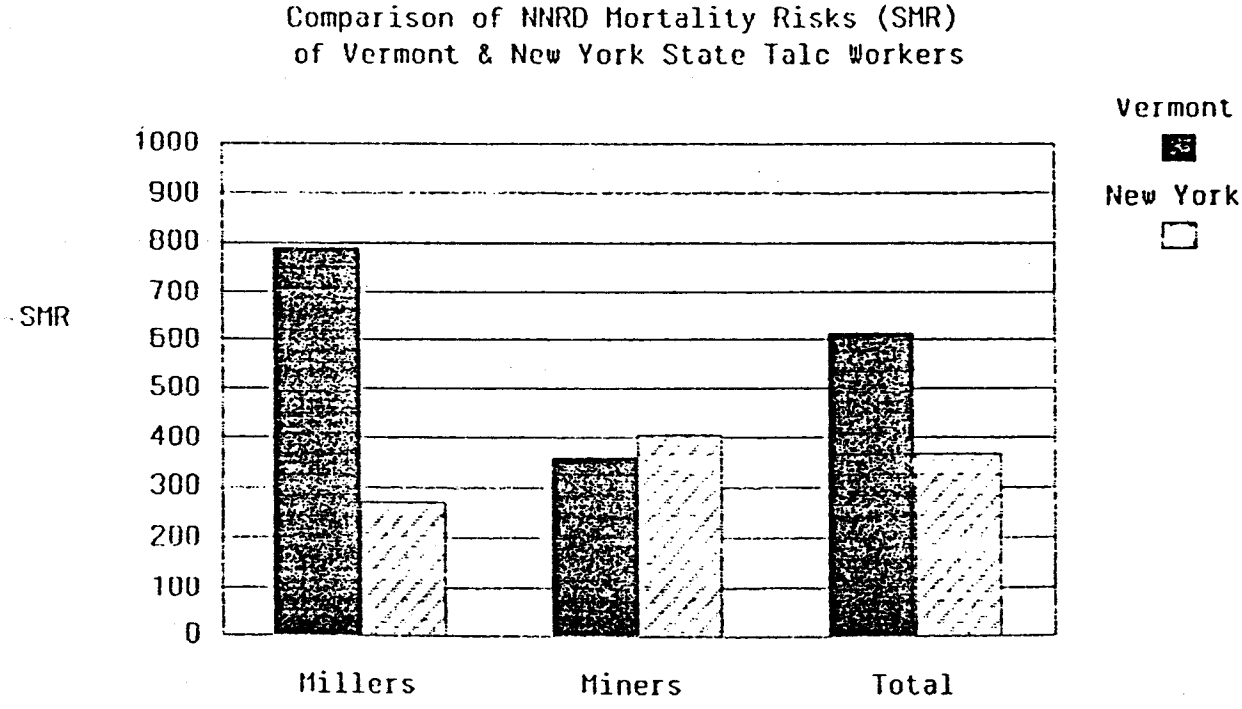


Figure 2



OSHA

TABLE Z-3 MINERAL DUSTS

Substance	mppcf[a]	mg/m³
Soapstone	20	
~~Talc (not containing asbestos)~~	20[c]	
Talc (containing asbestos) Use asbestos limit		
Tremolite, asbestiform (see 29 CFR 1910.1001)		
Portland cement	50	
Graphite (Natural)	15	
Coal Dust:		
Respirable fraction less than 5% SiO_2		$\frac{2.4\ mg/m^3[e]}{\%SiO_2+2}$
Respirable fraction greater than 5% SiO_2		$\frac{10\ mg/m^3[e]}{\%SiO_2+2}$
Inert or Nuisance Dust:[d]		
Respirable fraction	15	5 mg/m³
Total dust	50	15 mg/m³

Note—Conversion factors - mppcf X 35.3 = million particles per cubic meter = particles per c.c.

[a] millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques.

[b] The percentage of crystalline silica in the formula is the amount determined from airborne samples, except in those instances in which other methods have been shown to be applicable.

[c] Containing less than 1% quartz; if 1% quartz or more, use quartz limit.

[d] All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by this limit, which is the same as the Particulates Not Otherwise Regulated (PNOR) limit in Table Z-1.

[e] Both concentration and percent quartz for the application of this limit are to be determined from the fraction passing a size-selector with the following characteristics:

Aerodynamic diameter (unit density sphere)	Percent passing selector
2	90
2.5	75
3.5	50
5.0	25
10	0

The measurements under this note refer to the use of an AEC (now NRC) instrument. The respirable fraction of coal dust is determined with an MRE; the figure corresponding to that of 2.4 mg/m³in the table for coal dust is 4.5 mg/m³.

[Corrected at 58 FR 40191, July 27, 1993]

ACGIH

Substance [CAS No.]	ADOPTED VALUES TWA (ppm/mg/m³)	STEL/C (ppm/mg/m³)	Notations	Mol Wgt	TLV Basis—Critical Effect(s)
Talc (containing no asbestos fibers) [14807-96-6]	2 mg/m³ (e. i)	—	A4	—	Lung
Talc (containing asbestos fibers)	Use asbestos TLV–TWA[n]	C 2 mg/m³	—	—	Lung; asbestosis
Tantalum metal [7440-25-7] and oxide [1314-61-0] dusts, as Ta	5 mg/m³	—	—	180.95 441.90	Irritation; lung Irritation; lung
TEDP, *see* Sulfotep					
Tellurium [13494-80-9] and compounds, except hydrogen telluride, as Te	0.1 mg/m³	—	—	127.60	CNS; cyanosis; Liver
Tellurium hexafluoride [7783-80-4]	0.02 ppm	—	—	241.61	Irritation
Temephos [3383-96-8]	10 mg/m³	—	BEI	466.46	Cholinergic
TEPP [107-49-3]	0.05 mg/m³	—	Skin; BEI	290.20	Cholinergic
Terephthalic acid [100-21-0]	10 mg/m³	—	—	166.13	Lung
Terphenyls [26140-60-3]	—	C 5 mg/m³	—	230.31	Irritation
1,1,1,2-Tetrachloro-2,2-difluoroethane [76-11-9]	500 ppm	—	—	203.83	Liver; blood
1,1,2,2-Tetrachloro-1,2-difluoroethane [76-12-0]	500 ppm	—	—	203.83	CNS; pulmonary edema

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 28 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

John W. Kelse
Corporate Industrial Hygienist
R.T. Vanderbilt Company, Inc.
P.O. Box 5150
Norwalk, CN. 06856-5150

Dear Mr. Kelse:

Your letter of August 21, 1992 to Michael Beard concerning the regulations by the Environmental Protection Agency (EPA) for the Asbestos Hazard Emergency Response Act (AHERA) has been referred to this office for response.

As your letter indicates, the AHERA definition of asbestos is "the asbestiform varieties of: chrysotile (serpentine); crocidolite (riebeckite); amosite (cummingtonitegrunerite); anthophyllite; tremolite; and actinolite." This is also the definition used in EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) Asbestos Regulations. EPA does not regulate the non-asbestiform varieties of these minerals. In addition, EPA does not regulate "talc fiber, fibers of mixed mineral assemblage, fiberglass, camel hair or any other fiber or particulate" unless these materials contain asbestos in an amount greater than 1%. These materials would then be defined as "asbestos-containing material" by the AHERA regulations.

I hope this response will answer your inquiry. If you have any further questions, please contact Betty Weiner of my staff on (202)-260-3790.

Sincerely,

Diane Sheridan

Diane Sheridan, Chief
Abatement Programs Section

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Relation of Particle Dimension to Carcinogenicity in Amphibole Asbestoses and Other Fibrous Minerals [1,2]

Mearl F. Stanton, [3,4] Maxwell Layard, [5,6] Andrew Tegeris, [7] Eliza Miller, [3,8] Margaret May, [3,4] Elizabeth Morgan, [7,9] *and* Alroy Smith [5]

ABSTRACT—In 72 experiments, durable minerals in the form of particles on respirable size and of wide chemical and structural varieties, were implanted in the pleurae of outbred female Osborne-Mendel rats for periods of more than 1 year. The incidence of induced malignant mesenchymal neoplasms correlated well with the dimensional distribution of the particles. The probability of pleural sarcoma correlated best with the number of fibers that measured 0.25 μm or less in diameter and more than 8 μm in length, but relatively high correlations were also noted with fibers in other size categories having diameters up to 1.5 μm and lengths greater than 4 μm. Morphologic observations indicated that short fibers and large-diameter fibers were inactivated by phagocytosis and that negligible phagocytosis of long, thin fibers occurred. The wide variety of compounds used in these experiments suggested that the carcinogenicity of fibers depended on dimension and durability rather than on physicochemical properties.—JNCI 1981; 67:965-975.

Work in several laboratories has indicated that diverse varieties of minerals are carcinogenic when applied directly to the pleura of the rat or hamster in the form of microscopic fibers, i.e., particles with dimensional aspect ratios of 3:1 or greater (*1-9*). The same minerals are much less carcinogenic when applied at equal weight and size in nonfibrous form. Further, preliminary experiments indicate that carcinogenicity correlates best with increasing numbers of fibers having both diameters of 0.25 μm or less and lengths of more than 8 μm and that the correlation diminishes with fibers of greater diameter or lesser length. Consequently, a reasonable conclusion is that the long, thin, fibrous structure is critical to the carcinogenicity of these minerals. Studies on fibrous samples within very narrow dimensional ranges would be valuable in the establishment of this hypothesis, but these ideal samples are not available. Consequently, we are faced with the correlation of carcinogenicity with fiber samples of widely mixed dimension. The purpose of this report is to correlate our best estimate of fibrous dimension with carcinogenicity for all those minerals that we have studied that are both durable and within the size range of respirable particles. This involves 72 experiments with minerals of wide chemical and structural variety. Of special interest are the data on the amphibole asbestoses: amosite, tremolite, and crocidolite, though estimates of the dimensions of the asbestoses are especially liable to error. Chrysotile, although as carcinogenic as the amphiboles at comparable dimensions, could not be included since it has proved difficult to be measured with any degree of precision.

MATERIALS AND METHODS

None of the methods were appreciably different from those described in earlier papers (*1, 6, 9-11*). Consequently, only modifications of methods are detailed here. A standard 40-mg dose of particles uniformly dispersed in hardened gelatin was applied by open thoracotomy directly to the left pleural surface of 12- to 20-week-old, outbred female Osborne-Mendel rats. In each experiment, 30-50 rats were treated and followed for 2 years, at which time the survivors were killed. All rats were necropsied and all lesions examined histologically. A positive response was the occurrence of pleural sarcomas that resembled the mesenchymal mesotheliomas of man, developing after the 1st year (*12*). Three types of controls were considered: untreated rats, rats that received thoracotomies but no pleural implant, and rats with pleural implants of nonfibrous material. There were two types of spontaneous tumors that could cause confusion: the fibrosarcomas of left mammary glands and the subcutaneous fibrosarcomas induced by suture material. Vigilance and early surgical removal accounted for most mammary tumors; the use

ABBREVIATIONS USED: alumin = aluminum oxide; attapul = attapulgite(s); crocid = crocidolite(s); dawson = dawsonite(s); halloy = halloysite(s); UICC = International Union Against Cancer; wollaston = wollastonite(s).

[1] Received November 13, 1980; revised May 6, 1981; accepted June 8, 1981.

[2] The guidelines for the care and use of laboratory animals were followed as set forth by the Committee on Revision of the Guide for Laboratory Animal Facilities; by the Guide for the Care and Use of Laboratory Animal Resources, the National Research Council; and by the National Institutes of Health.

[3] Laboratory of Pathology, Division of Cancer Biology and Diagnosis, National Cancer Institute (NCI), National Institutes of Health, Public Health Service, U.S. Department of Health and Human Services, Bethesda, Md. 20205.

[4] Deceased.

[5] Biometry Branch, Division of Cancer Cause and Prevention, NCI.

[6] *Address reprint requests to* Dr. Layard *at his present address:* Veterans Administration Medical Center, 3801 Miranda Ave., Palo Alto, Calif. 94304.

[7] Pharmacopathics Research Laboratories, Inc., 9705 North Washington Blvd., Laurel, Md. 20810.

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[9] *Present address:* Triangle Resource Industries, P.O. Box 599, Laurel, Md. 20707.

of synthetic, biodegradable, polyglycolic acid sutures largely eliminated suture sarcomas. An equivocal diagnosis for the origin of a tumor was necessary in less than 1% of the tumors. The probability of pleural sarcoma in each experiment was calculated by an actuarial life table method that accounts for early deaths without pleural sarcoma and provides a good means of making quantitative comparisons of one experiment with another. Details of this method are given in (*13, 14*).

The fibrous materials used in these experiments were mostly commercial products that were submitted by the manufacturers from an interest in their potential carcinogenicity. Consequently, they were used as received and were not especially refined except in our efforts to separate particles by size. None of the preparations appeared overtly contaminated by other materials when examined in the electron microscope. A few of the small-fibered subfractions of the fibrous materials were obtained by ball milling in a steel ball mill and consequently were contaminated with fragments of steel. In general, subfractions were obtained by simple gravimetric methods in aqueous media to separate fibers of different dimensions. These maneuvers included sedimentation, centrifugation, and filtration, which in some instances were also responsible for the reduction of the size of the particles but did not otherwise alter the particles physically or chemically. Eleven chemically and structurally different groups of fibers were available for study, and samples studied are listed in text-figure 1 and table 1. Six major groups of particles had multiple dimensional ranges; these include: crocidolites: (samples crocid 1-13), glasses (glass 1-22), aluminum oxide whiskers (alumin 1-8), talcs (talc 1-7), dawsonites (dawson 1-7), and wollastonites (wollaston 1-4). Seven additional types of particles had only one or two dimensional ranges. These were the amphibole asbestoses tremolite (tremolite 1, 2) and amosite, the clays attapulgite (attapul 1, 2) and halloysite (halloy 1, 2), crystals of silicon carbide and potassium titanate (titanate 1, 2), and nickel titanate (titanate 3). All of these materials have been described elsewhere (*4, 6, 10, 11, 15-18*), but the following information is pertinent.

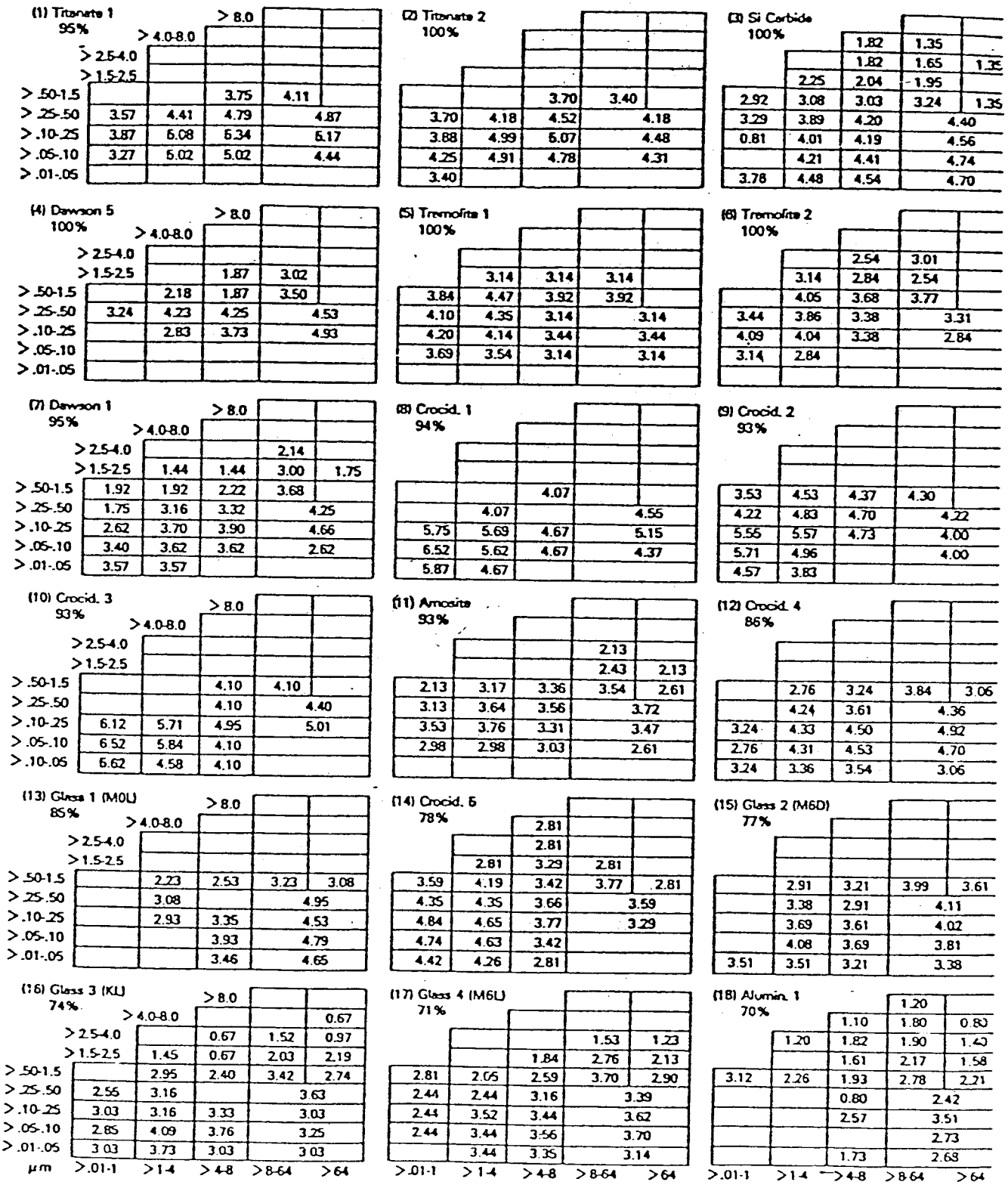
Crocidolite (crocid 1-13).—These 13 samples of South African crocidolite (an amphibole asbestos) were from four different sources. Samples crocid 1, 3, and 9 were prepared in our laboratory from a single sample of hand-cobbed, unmilled ore. The ore sample was hand milled without exposure to any metallic materials and reduced to the approximate size of commercial crocidolite. Samples crocid 6, 7, 8, 11, 12, and 13 were all prepared in our laboratory by various milling, sedimentation, and flotation methods from a single lot of standard UICC crocidolite designated crocid 5. Differences in dimension were the result of different milling times. Crocid 5, the original UICC sample, has been characterized in (*19, 20-23*). Samples crocid 4 and 10 were specimens prepared in a commercial laboratory from a single separate sample of South African crocidolite and separated by centrifugation to obtain mutually exclusive size ranges from the same sample (*24*). The remaining sample, crocid 2, was obtained from Dr. J. C. Wagner (Medical Research Council Pneumoconiosis Unit, Penarth, Wales) as representative of the material used by him in his original experiments (*25*). It was our impression that any mechanical manipulation of these samples could both reduce the size of the particles by fragmentation and effectively increase the size of the particles by clumping. For this reason, probably the dimensional measurements on crocidolite are the least representative of all the fibers measured.

Glass (glass 1-22).—The first 18 of the 22 glasses were borosilicate glasses that have been previously reported and can be recognized from those publications by their letter designations (*4, 10*). Glasses 12, 14, 15, and 18 were preparations of typical large-diametered insulation glass fibers that were coated with a phenol-formaldehyde binder. In the early experiments, glass 18 was used as a control and also served as a vehicle for the implants. Glasses 19 and 20 were preparations of large-diametered fibrous glass that was leached to remove all elements except SiO_2. These two glasses were exceptionally fragile and contained many irregular fragments. Glasses 21 and 22 were large-diametered extruded fibers with a microcrystalline aluminum oxide content greater than 80% (glass 21) and with a microcrystalline zirconium oxide content greater than 90% (glass 22).

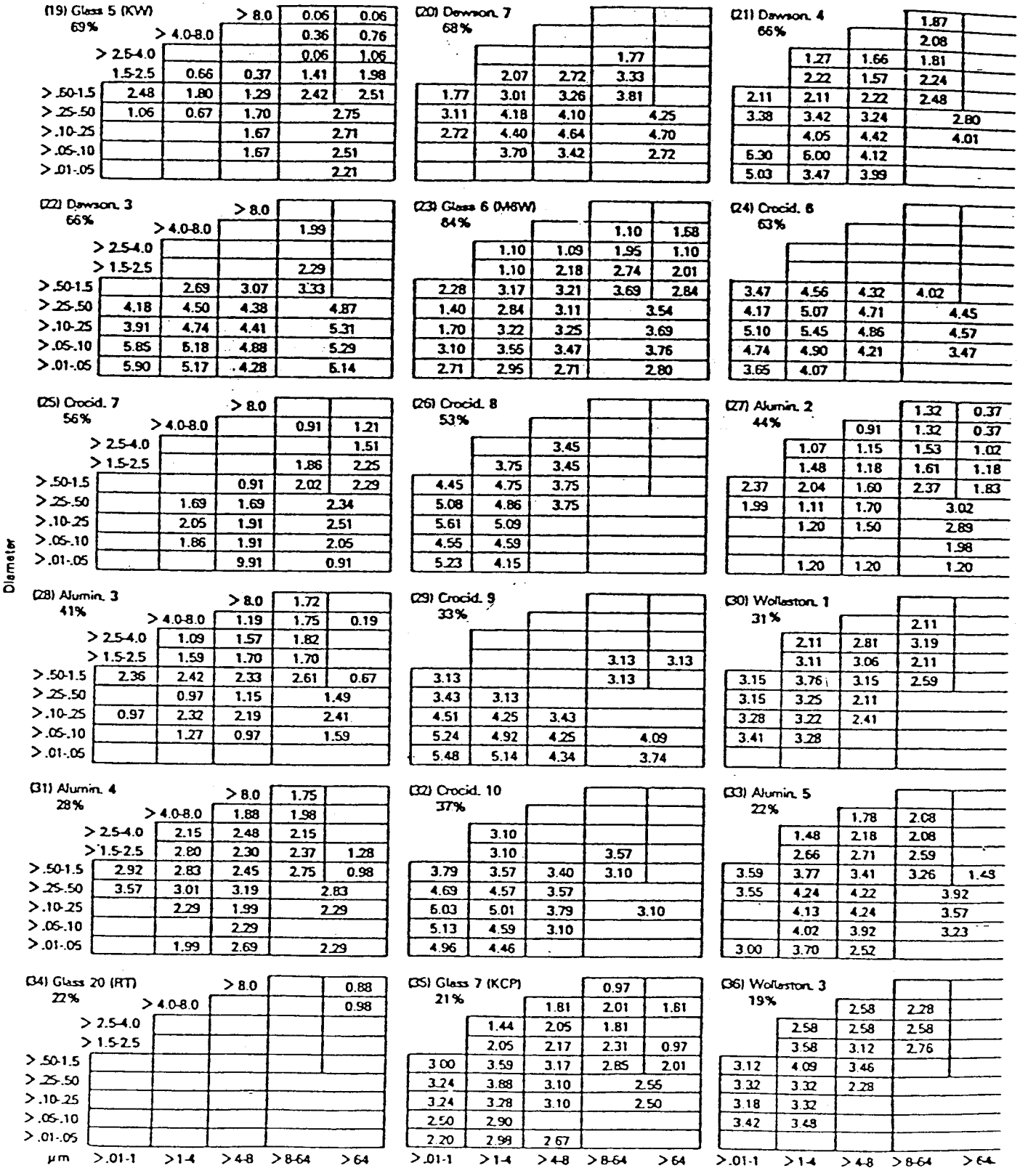
Aluminum oxide (alumin 1-8).—The 8 samples of aluminum oxide were all crystalline sapphire whiskers prepared by General Technologies Corporation, Reston, Va., or by Thermokinetics Fiber Incorporated, Nutley, N.J. (*15-18, 26*). All of the samples were processed and selected for dimensional ranges. Of the samples, 3 were exceptionally noteworthy. Sample alumin 8 was nonfibrous, sample alumin 3 was exceptionally fine but tended to cluster in nonfibrous balls, and sample alumin 4 contained whiskers of aluminum nitride as well as aluminum oxide.

Talcs (talc 1-7).—All seven talcs were refined raw materials for commercial products. Each was from a separate and diverse source and selected to include all extreme ranges of dimension. Platelike structure was consistent and was considered in the calculation of the volume (*15-18*).

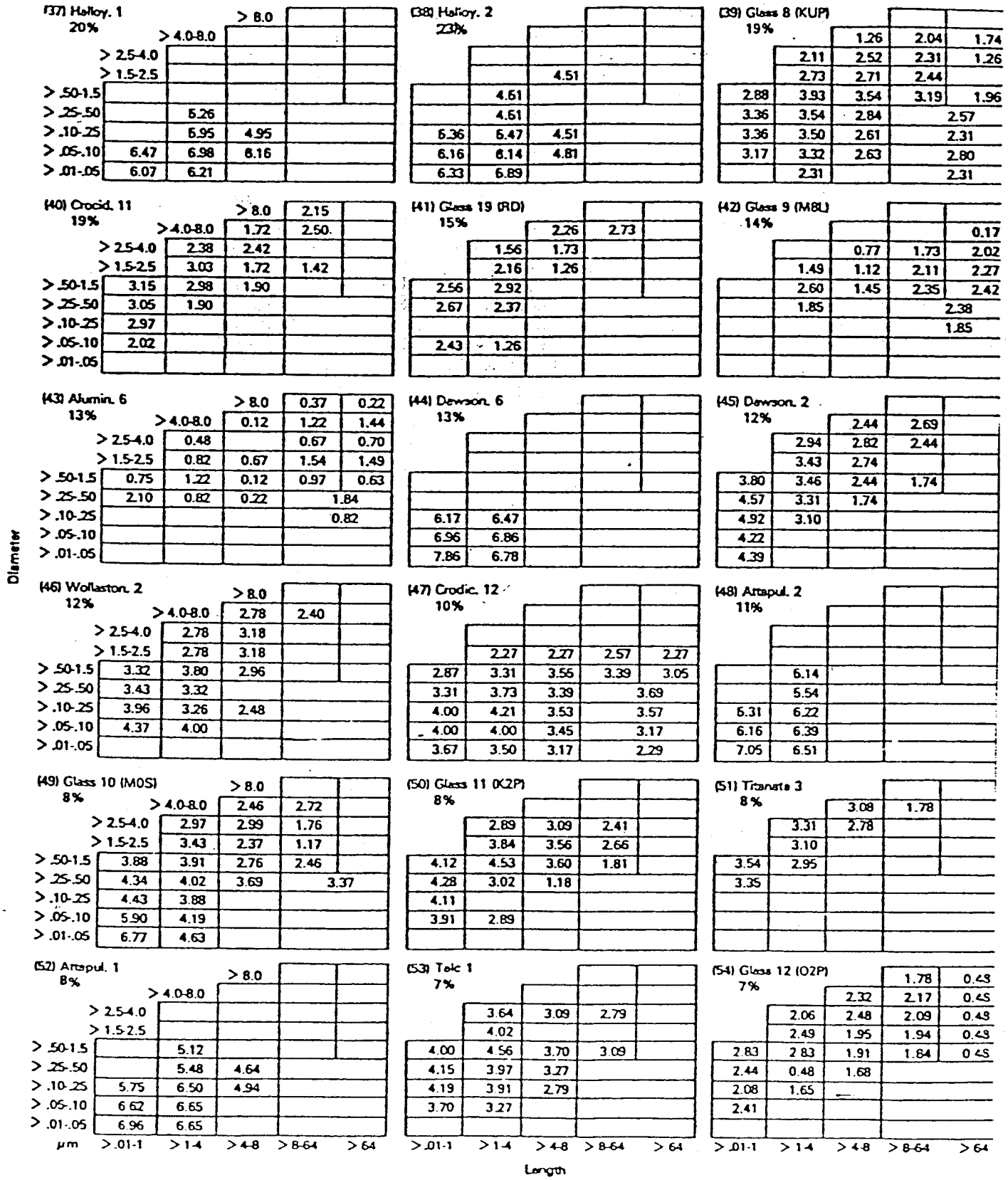
Dawsonite (dawson 1-7).—The 7 dawsonite samples (crystalline dehydroxy sodium aluminum carbonate $[NaAl(OH)_2CO_3]$ were from several sources. The characteristics and synthesis of dawsonite can be found in (*27, 28*). Samples dawson 2 and 3 were synthetic crystals prepared by a commercial company (for dawson 2) and by the Bureau of Mines, U.S. Department of Interior (for dawson 3). Sample dawson 4 was a natural crystalline dawsonite from the Olduvai Gorge, Tanzania. The remaining 4 samples (dawson 1, 5, 6, and 7) were synthetic crystals from a second commercial company. These 4 samples were especially crystallized and sorted to achieve narrow ranges of size.



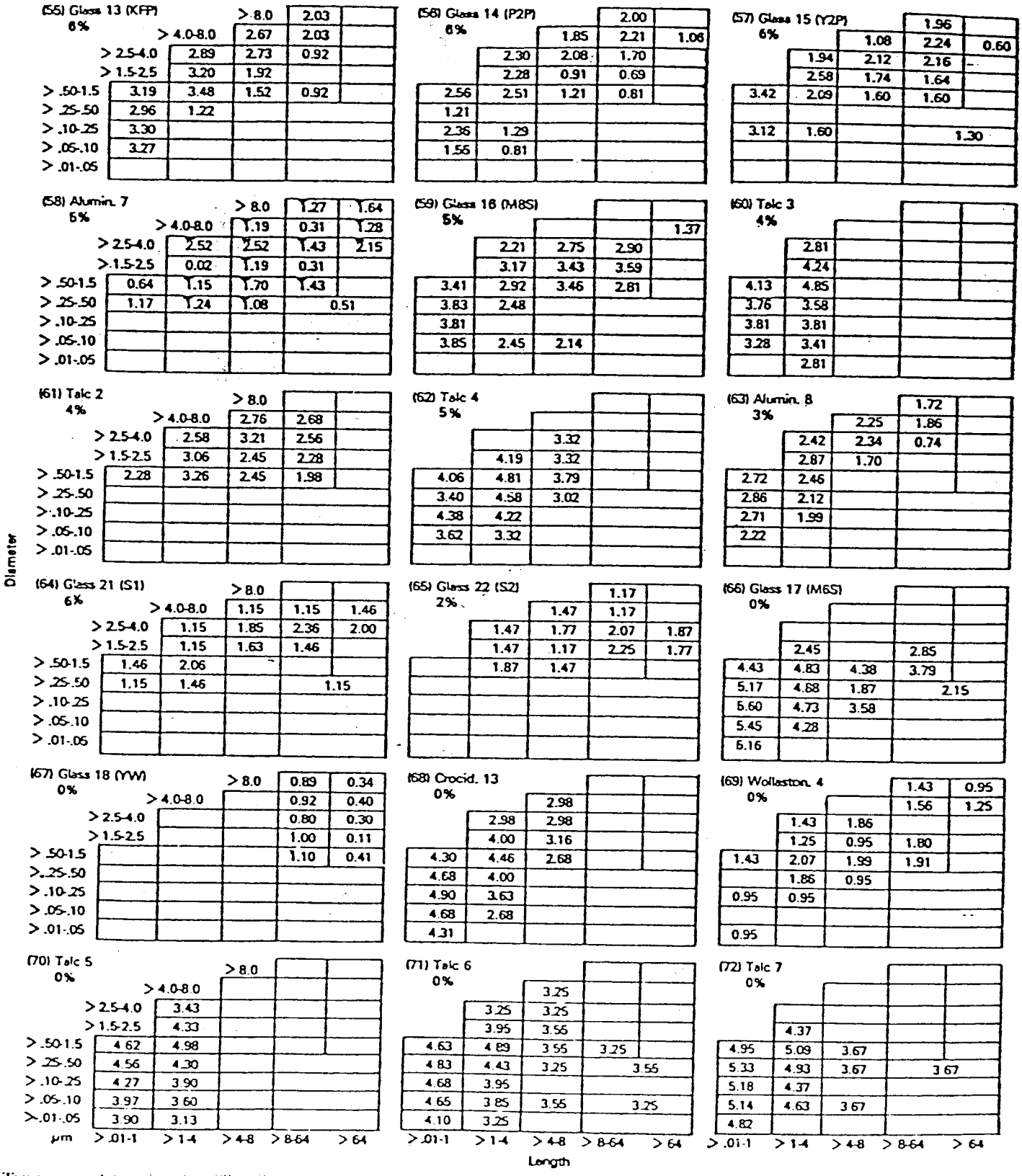
TEXT-FIGURE 1.—Fiber distribution by common log of the number of particles per microgram in each of 34 dimensional categories.



TEXT-FIGURE 1 *(continued).*—Fiber distribution by common log of the number of particles per microgram in each of 34 dimensional categories.



TEXT-FIGURE 1 (*continued*).—Fiber distribution by common log of the number of particles per microgram in each of 31 dimensional categories.



TEXT-FIGURE 1 (*continued*).—Fiber distribution by common log of the number of particles per microgram in each of 34 dimensional categories.

TABLE 1.—*Summary of 72 experiments with different fibrous materials*

Expt No.	Compound	Actual tumor incidence	Percent tumor probability ± SD	Common log fibers/μg, ≤0.25 μm × >8 μm
1	Titanate 1	21/29	95±4.7	4.94
2	Titanate 2	20/29	100	4.70
3	Si carbide	17/26	100	5.15
4	Dawson 5	26/29	100	4.94
5	Tremolite 1	22/28	100	3.14
6	Tremolite 2	21/28	100	2.84
7	Dawson 1	20/25	95±4.8	4.66
8	Crocid 1	18/27	94±6.0	5.21
9	Crocid 2	17/24	93±6.5	4.30
10	Crocid 3	15/23	93±6.9	5.01
11	Amosite	14/25	93±7.1	3.53
12	Crocid 4	15/24	86±9.0	5.13
13	Glass 1	9/17	85±13.2	5.16
14	Crocid 5	14/29	78±10.8	3.29
15	Glass 2	12/31	77±16.6	4.29
16	Glass 3	20/29	74±8.5	3.59
17	Glass 4	18/29	71±9.1	4.02
18	Alumin 1	15/24	70±10.2	3.63
19	Glass 5	16/25	69±9.6	3.00
20	Dawson 7	16/30	68±9.8	4.71
21	Dawson 4	11/26	66±12.2	4.01
22	Dawson 3	9/24	66±13.4	5.73
23	Glass 6	7/22	64±17.7	4.01
24	Crocid 6	9/27	63±13.9	4.60
25	Crocid 7	11/26	56±11.7	2.65
26	Crocid 8	8/25	53±12.9	0
27	Alumin 2	8/27	44±11.7	2.95
28	Alumin 3	9/27	41±10.5	2.47
29	Crocid 9	8/27	33±9.8	4.25
30	Wollaston 1	5/20	31±12.5	0
31	Alumin 4	4/25	28±12.0	2.60
32	Crocid 10	6/29	37±13.5	3.09
33	Alumin 5	4/22	22±9.8	3.73
34	Glass 20	4/25	22±10.0	0
35	Glass 7	5/28	21±8.7	2.50
36	Wollaston 3	3/21	19±10.5	0
37	Halloy 1	4/25	20±9.0	0
38	Halloy 2	5/28	23±9.3	0
39	Glass 8	3/26	19±10.3	3.01
40	Crocid 11	4/29	19±8.5	0
41	Glass 19	2/28	15±9.0	0
42	Glass 9	2/28	14±9.4	1.84
43	Alumin 6	2/28	13±8.8	0.82
44	Dawson 6	3/30	13±6.9	0
45	Dawson 2	2/27	12±7.9	0
46	Wollaston 2	2/25	12±8.0	0
47	Crocid 12	2/27	10±7.0	3.73
48	Attapul 2	2/29	11±7.5	0
49	Glass 10	2/27	8±5.6	0
50	Glass 11	1/27	8±5.5	0
51	Titanate 3	1/28	8±8.0	0
52	Attapul 1	2/29	8±5.3	0
53	Talc 1	1/26	7±6.9	0
54	Glass 12	1/25	7±5.4	0
55	Glass 13	1/27	6±5.7	0
56	Glass 14	1/25	6±5.5	0
57	Glass 15	1/24	6±5.9	1.30
58	Alumin 7	1/25	5±5.1	0
59	Glass 16	1/29	5±4.4	0
60	Talc 3	1/29	4±4.3	0
61	Talc 2	1/30	4±3.8	0
62	Talc 4	1/29	5±4.9	0
63	Alumin 8	1/28	3±3.4	0
64	Glass 21	2/47	6±4.4	0
65	Glass 22	1/45	2±2.3	0
66	Glass 17	0/28	0	0
67	Glass 18	0/115	0	0
68	Crocid 13	0/29	0	0
69	Wollaston 4	0/24	0	0
70	Talc 5	0/30	0	0
71	Talc 6	0/30	0	3.30
72	Talc 7	0/29	0	0

RTV talc

They represent an excellent size distribution for comparison.

Wollastonite (wollaston 1-4).—Wollastonite is a naturally occurring crystalline fiber of monocalcium silicate (*15-18*). Four separate samples of this substitute for asbestos were received from the same Canadian mine. These were graded commercially according to size by the designation A, B, D, and F. It was apparent at low-power magnification that only grade F was completely fibrous and that these fibers were relatively large.

Tremolite (tremolite 1, 2).—The second type of amphibole asbestos studied was tremolite, a material that has a close affinity to the talcs. Both of these samples were from the same lot of asbestos and were in the optimal range of size for carcinogenesis. Comparison of these fibers indicated that they were distinctly smaller in diameter than the tremolite fibers used by Smith et al. (*29*).

Amosite.—The third amphibole asbestos studied was a single sample of South African amosite from the UICC standard reference samples. No efforts were made to alter this as received, and descriptions of this sample as published should apply (*19, 21, 22*).

Attapulgite (attapul 1-2).—Of the natural fibers, the clay attapulgite was of particular interest because of its use in many household items that generate respirable dust. Two different samples of this complex hydrated magnesium silicate were obtained from sources in Attapulgus, Decatur County, Georgia. Both samples were considerably refined, and by electron microscopy they were seen to be composed entirely of short fibers of consistently small diameter (*30*). These refined clays were considered by the U.S. Bureau of Mines to be 90% or greater in purity, with the remaining 10% being quartz.

Halloysite (halloy 1-2).—Halloysite is a natural fibrous hydrated aluminum silicate, which is respirable and of minute size. The 2 samples were obtained from Dr. Walter Parham, who recovered them from the raw water supply of Hong Kong. On examination these samples were seen to have a tendency for clumping in water. In an effort to disperse the minute fibers, the second sample was sonicated and treated with sodium

hexametaphosphate. Clumping persisted in this second sample, and little different was seen between the 2 samples.

Silicon carbide (si carbide).—One metallic crystalline whisker other than alumin was prepared by the General Technologies Corporation. Silicon carbide was a single sample, which was of exceptionally fine, uniform dimension.

Potassium octatitanate (titanate 1-3).—In addition to the synthetic crystals of dawsonite, aluminum oxide, and silicon carbide, 2 samples of fibrous crystalline potassium octatitanate (titanate 1 and 2) were tested. These were obtained from two different suppliers but they represent a single source. Because of the potential carcinogenicity of metallic nickel, the control for these 2 samples was nonfibrous, finely ground nickel titanate (titanate 3).

The 72 experiments represent all of the experiments done in a single dose range and with durable minerals and particles in the respirable range. Additional controls outside of these limits are mentioned in "Results."

Fiber measurements.—An aliquot of each of the 72 experimental mineral samples was placed on a Formvar-covered, slotted grid with an opening measuring 1×2 mm. This grid was air dried and first examined under the light microscope. If the fibers appeared satisfactorily distributed, a photomontage of the entire grid was made at a final magnification of ×3,000. The slotted grid was then placed in a Siemens electron microscope, Elmiskop 1-A, and the entire grid was scanned at low magnification. From this scan, an area that seemed to represent a typical distribution of particles in the specimen was selected for counting. At a final magnification of about ×5,000-100,000, a second photomontage was made of that section of the grid selected to include particles typical of the sample. This selected area, which generally measured about 350×150 μm, was then located on the lower magnification montage of the grid and examined to determine whether the area chosen was truly representative of the entire grid. Finally, all fibers in the area were counted and measured individually. For the diameters, a comparative scale at the final magnification was used to measure magnified diameters that measured less than 1 mm. In most cases, the selected area counted included at least 1,000 fibers, but the actual number varied with the overall size of the particles.

Subsequently, with the aid of the IBM system 370 computer, assuming the fibers to be of cylindrical shape and using the density of the material, we were able to estimate the weight of the counted samples and the number of particles of a given dimension in the 40-mg dose administered. For the purpose of calculation, particles were grouped into 34 dimensional ranges as indicated in text-figure 1, and the number of particles per microgram in each category was calculated. Duplicate counts on the montages were done on most samples and were surprisingly similar, as were counts on different areas of the same montage. However, when studies of repeat samples from the original fibers were made, considerable variation in counts occurred. Clearly, the method is subject to several errors; calibration of the electron microscope, deviation of particles from the assumed cylindrical shape, and sampling errors, especially where large particles are concerned, represent the major problems. Nevertheless, the estimates are probably valid to within one order of magnitude. Consequently, the counts are reported as the common log with the characteristic of the log representing the probable limit of accuracy (text-fig. 1).

RESULTS

Controls have been discussed in previous publications (*4, 6, 9-11*), but they were approached here in a slightly different way. In addition to untreated controls we studied rats in which open thoracotomy was performed and a noncarcinogenic material was either applied to the pleura or implanted in the lung. These 3 groups (table 2) were rats from numerous experiments that were of the same species, sex, and age and that were housed in the same quarters. The incidence of clearly apparent pleural neoplasms in untreated, aged outbred Osborne-Mendel female rats was essentially nonexistent. However, a few pleomorphic sarcomas that might be confused with pleural tumors occurred in the left thorax of both treated and, to a lesser degree, untreated controls. Although these tumors involved the thickness of the chest wall, in most cases the tumors appeared to be derived either from mammary gland fibroadenoma or from suture granuloma in the subcutaneous tissues. But there remained a few tumors for which no definite origin could be determined and which were histologically comparable with pleural sarcomas. In both the experimental groups and the control groups these questionable tumors were counted as pleural sarcomas. These essentially confusing tumors observed in the controls need to be taken into account in the assessment of the carcinogenicity of the experimental materials. The incidence of pleural sar-

TABLE 2.—*Incidence of pleural sarcomas in outbred female Osborne-Mendel control rats*

Time, wk	Untreated[a]	Noncarcinogenic pulmonary implants[a]	Noncarcinogenic pleural implants[a]	Combined controls[a]
12-52	1/113	0/49	0/47	1/209
53-65	0/15	2/26	1/72	3/113
66-78	0/26	4/50	3/64	7/140
79-91	0/68	1/70	2/85	3/223
92-104	0/26	1/72	10/294	11/392
105-120	0/98	1/162	—1/36	2/296
121-130	1/66	0/3		1/69
131-143	0/27			0/27
144-156	0/27			0/27
156	1/22			1/22
Total	3/488	9/432	17/598	29/1,518
Percent	0.6	2.1	2.8	1.9

[a] No. dead with pleural sarcomas/No. dead without pleural sarcomas.

comas in all 3 control groups combined, calculated by the life table method (*13*), was 7.7±4.2%. Comparison of this incidence with the pleural sarcoma incidence in the 72 individual experiments showed that the incidence of pleural sarcomas in a particular experimental group was significantly greater than that in the combined control group only if it exceeded 30% (*see* expts 1–29 in table 1).

In regard to the controls, some negative experiments with intrapleural implants not used as controls should be mentioned. These experiments included intrapleural implants that did not conform to the type of materials under consideration because the particles were either nondurable (cotton lint, gypsum, and carrageenan), were of greater than respirable size (steel shavings, steel wool, vermiculite, polyurethane, tungsten carbide, and infusorial earth), or were exclusively nonfibrous (polyacrylic nitrile, antigorite, silicon dusts, and several glasses). None of these experiments had an incidence of pleural sarcoma that was significantly greater than the 7.7% incidence of the combined control group.

From the summarization of the 72 experiments in table 1 and text-figure 1, even cursory examination of the fiber distribution suggested that particles in the relatively thin- and long-dimensional categories were associated with higher tumor probabilities. This observation was confirmed by the statistical correlation and regression techniques that were used in previous papers (*4, 9, 10*). The logit transformation (*13*) was applied to the estimated tumor probabilities (p) according to the formula: Logit$=\ln [p/(1-p)]$, where ln denotes the natural logarithm. The 34 dimensional categories indicated in text-figure 1 were arbitrarily grouped into 11 larger categories, and the simple correlation coefficients of the logit of tumor probability with the common logarithms of numbers of particles per microgram in each of these categories was calculated (*see* table 3). The maximum correlation coefficient, 0.80, was with particles equal to or less than 0.25 μm in diameter and greater than 8 μm in length. There was no correlation with particles equal to or less than 4 μm in length or with particles greater than 1.5 μm in diameter, but relatively good correlations were noted with log numbers of fibers in categories greater than 4 μm in length and up to 1.5 μm in diameter, with correlation coefficients of 0.45–0.80.

The possibility of the existence of relationships between the particle size distributions and tumor probabilities, which are not disclosed by the simple correlation coefficients in table 3, was explored by multiple regression methods. These methods were used to find the best-fitting function of the form: logit$=a+b_1 x_1 + \ldots + b_k x_k$, where $x_1, \ldots, x_k$ represent the common logs of numbers of the particles per microgram in the size categories of table 3, and $a, b_1, \ldots, b_k$ are the regression coefficients to be estimated. The analysis indicated that the addition of further dimensional categories to the category with diameter equal to or less than 0.25 μm and with length greater than 8 μm did not significantly improve the explanation of the variation in tumor probability. The regression equation for the single variable (x) representing the common log of number of particles per microgram with diameters equal to or less than 0.25 μm and lengths greater than 8 μm was:

$$\ln[p/(1-p)] = \underset{(0.24)}{-2.62} + \underset{(0.0834)}{0.9305}x.$$

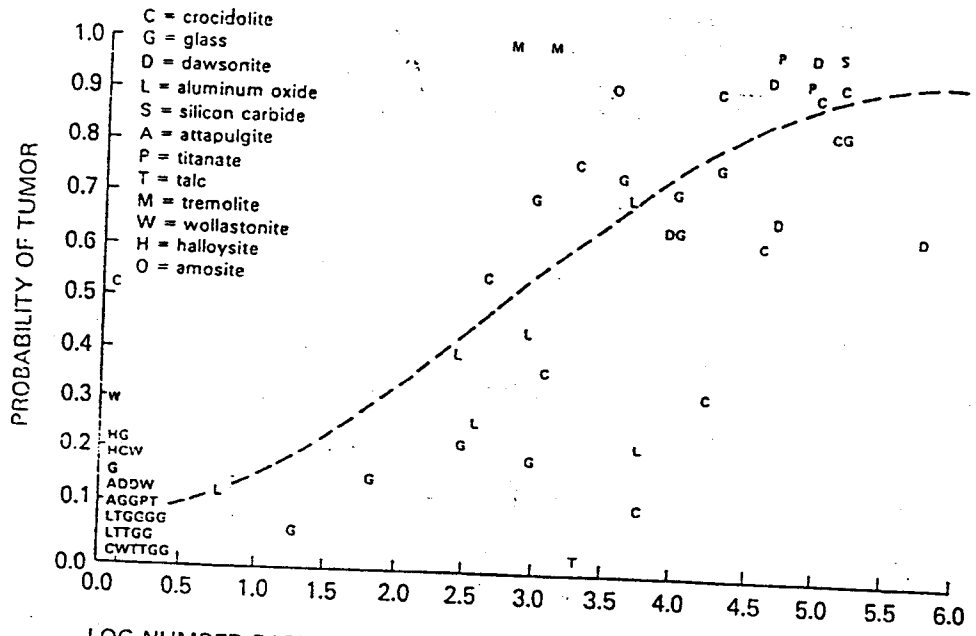
The *numbers in parentheses* beneath the regression coefficients are their estimated standard deviations. The relationship expressed by the above equation is highly significant ($P<0.0001$). The estimated regression curve is illustrated in text-figure 2.

The fact that the use of additional dimensional categories did not significantly improve the fit of the regression equation does not indicate lack of carcinogenicity in other categories. The regression of logit of tumor probability on common log of numbers of particles in other categories with a diameter up to 1.5 μm and a length greater than 4 μm would also indicate a highly significant relationship. The difficulty here is that the numbers of particles in adjacent size categories were highly correlated. Better definition of the critical range of carcinogenicity would require more narrowly defined samples (i.e., particles in a narrower dimensional range). What is perhaps more likely than the existence of a narrow range of sizes within which particles are carcinogenic and outside of which they are not is that the probability of tumor falls as particle diameter increases and length decreases.

Of the 72 experiments, 7 had tumor incidences that deviated markedly from those predicted by the estimated regression line. These were: experiments 5 (tremolite 1), 6 (tremolite 2), 26 (crocid 8), 29 (crocid 9), 33 (alumin 5), 47 (crocid 12), and 71 (talc 6) (*see* table 1 and text-fig. 2). For the first 3 of these experiments the observed responses were higher than the predicted responses, but the high responses can in part be explained by the fact that there were substantial numbers of fibers in size categories adjacent to the category used in the regression equation. For the remaining 4 experiments, the observed response was substantially lower than the expected response; although no apparent explanation existed for these deviations, they were possibly due to inaccuracies in the assessment of functional particle size. In preparations of amphibole asbestoses (which included the crocidolites and tremolites), we observed that both

TABLE 3.—*Correlation coefficients of logit of tumor probability with common logarithm of number of particles per microgram in different dimensional ranges*

Fiber diameter, μm	Fiber length, μm		
	≤4	>4–8	>8
>4	—	−0.28	−0.30
>1.5–4	−0.45	−0.24	0.13
>0.25–1.5	0.01	0.45	0.68
≤0.25	0.20	0.63	0.80



TEXT-FIGURE 2.—Regression curve relating probability of tumor to logarithm of number of particles per μg with diameter ≤0.25 μm and length >8 μm.

clumping and fragmentation of the particles were greater than those in the other minerals, and estimates of particle size distribution in duplicate samples varied most for amphibole asbestoses.

DISCUSSION

The results show that a wide variety of compounds that seem to have only dimension and durability in common are carcinogenic for the pleura of the rat. Our conclusions regarding those dimensional categories that correlate strongly with probability of pleural tumor remain essentially the same as in previous studies, namely, that probability of pleural sarcoma correlates best with fibers that measure ≤0.25 μm×>8 μm, but that relatively high correlations were also observed with fibers in other categories having a diameter up to 1.5 μm and a length greater than 4 μm. A more refined estimate of critical carcinogenic dimension may be possible if the parameters of the experiments were changed. A different animals species, lower dose, more precise means of fiber measurement, more accurate volumetric calculations, and samples with narrower dimensional ranges all might be determining factors in better assessment of the particle dimensions critical to carcinogenicity. However, we should keep in mind two points: *a*) the dimensional limits are probably far from absolute, and *b*) we are dealing with cancer in the rat and thus extrapolation to man may not be precise.

It is clear from the histologic studies of these experiments and of previous studies that our data offer an explanation more for the lack of carcinogenicity of short fibers and thick fibers than for the carcinogenicity of long, thin fibers. Sections of preneoplastic pleural lesions show avid phagocytosis of both short fibers and large-diameter fibers but negligible phagocytosis of long, thin fibers. Consequently, in these experiments we may simply be measuring the efficiency of phagocytosis. Doubtless, we have little real knowledge of the way that long, thin fibers can cause cancer, but as Rous (*31*) once said, "Since what we think largely determines what we do, it is well that we think something." In the spirit of this quote, it might be profitable to consider potential mechanisms of cancer production by long, thin fibers. Of first importance are those hypotheses in which the progenitor of the cancer cell is not directly affected by the fiber. The long latent period would suggest that a generalized alteration either in local milieu or systemic environment might be at fault. In this regard, the abundant collagen in the preneoplastic pleural scars should be noted. Consideration of a relationship between this phenomenon and "solid-state" carcinogenesis is attractive, though the reduction of plastic sheets to small particles tends to reduce carcinogenesis. Mechanisms of solid-state carcinogenesis have been thoroughly reviewed by Brand (*32*), and little more need be added.

Any hypothesis concerning fibers must take into account the fact that both short fibers and thick fibers are less carcinogenic than fine, long fibers. Since dose was fixed in weight, but was different in dimension for all experiments, one might consider the surface area as a possible factor. If this were the case then fibers from the same pool that were modified only by shortening should be equal in tumor-producing capacity. Clearly, this is not true in the following experiments: 13 (glass 1, MOS) vs. experiment 49 [glass 10, MOS *see* (*4, 10*)].

and in experiment 24 (crocid 6) and experiment 25 (crocid 7) vs. experiment 40 (crocid 11), experiment 47 (crocid 12), and experiment 68 (crocid 13). However, in these examples the phagocytosis variable cannot be ruled out.

A provocative explanation relates to the ability of fine, long fibers to penetrate cells without killing them. That this can occur is evident from in vitro studies (*33*). However, simple penetration of cells by mycelia of fine dimension (a notable aspect of contamination of cell cultures by fungi) rarely produces transformation of cell cultures and thus is unlikely to produce cancer. However, mineral fibers differ from fungi in their rigidity as well as chemical content, and one easily could conceive of physical differences between the mineral fibers and mycelia that might be critical.

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Mr. Kelly Bailey
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October 8, 1990

Dear Mr. Bailey;

As your requested, I have examined the samples reported by Merle Stanton as Talc 6 and Tremolite I and II. Talc 6 is identified by Stanton's notes as Nytal 300. This sample was implanted in his experimental animals on 4-16-73. According to Stanton's notes, the tremolite sample was received from Johns Manville and was from California. It was implanted on 10-26-71 and again in 8/75. It is, therefore, both tremolite I and II. I received these samples from Dr. Lewis Lipkin and Ms. Marta Wade at the National Cancer Institute.

Both samples were prepared in the same manner for observation under the SEM. About 0.002g of material was dispersed in distilled water and collected on a 0.1 micrometer Nucleopore filter. After drying, a portion of the filter was placed on a polished Al SEM stub and coated with AuPd.

TREMOLITE I AND II

Photographs were taken from randomly selected places on the filter and 5000X and at some lower magnification between 2000X and 750X. Widths were measured from the 5000X photographs and lengths were measured from either the 5000X or lower magnification depending upon the length. From three photographs, all particles longer than 1 micrometer were measured. From three additional photographs, only particles with lengths of at least 4 micrometers were measured.

For 90 particles longer than 4 micrometers the following width and length distribution was found:

width (μm)	percent	length (μm)	percent
< 0.25 μm	4		
≤ 0.5 - 0.25	51	4 - ≤ 6	48%
≤ 1.0 - 0.5	34	>6 - ≤ 10	30
≤ 1.5 - 1.0	9	> 10 - ≤ 20	12
> 1.5	2	< 20	10

The photographs and overlays indicating which particles were measured are attached.

Some, but not all of the particles that are wider than 1.0 μm are striated or have splayed ends. All particles longer than 4 micrometers have aspect ratios greater than 3:1. 71% have aspect ratios of 10:1 or greater. The average aspect ratio is 18:1.

TALC 6

This sample was measured directly from the screen of the SEM. A random location was taken on the filter and every particle longer than 4 micrometers that crossed the center of the field on a traverse was measured at 5000X magnification, decreasing as necessary for long lengths. On every particle measured, an EDS was taken. All particles with significant Mg, Si and Ca peaks were identified as tremolite. All other compositions were identified as other.

46% of the particles measured were identified as tremolite.

49% of the tremolite particles have aspect ratios of at least 3:1.

The width and length of the tremolite particles is as follows:

width (μm)	percent	length (μm)	percent
< 0.5	0	≥ 4.0 - < 6.0	6
≥ 0.5 - < 1.0	6	≥ 6.0 - < 8.0	10
≥ 1.0 - < 2.0	10	≥ 8.0 - < 10.0	20
≥ 2.0 - < 3.0	6	≥ 10.0 - < 20.0	38
≥ 3.0 - < 4.0	29	> 20.0	26
≥ 4.0 - < 5.0	22		
> 5.0	27		

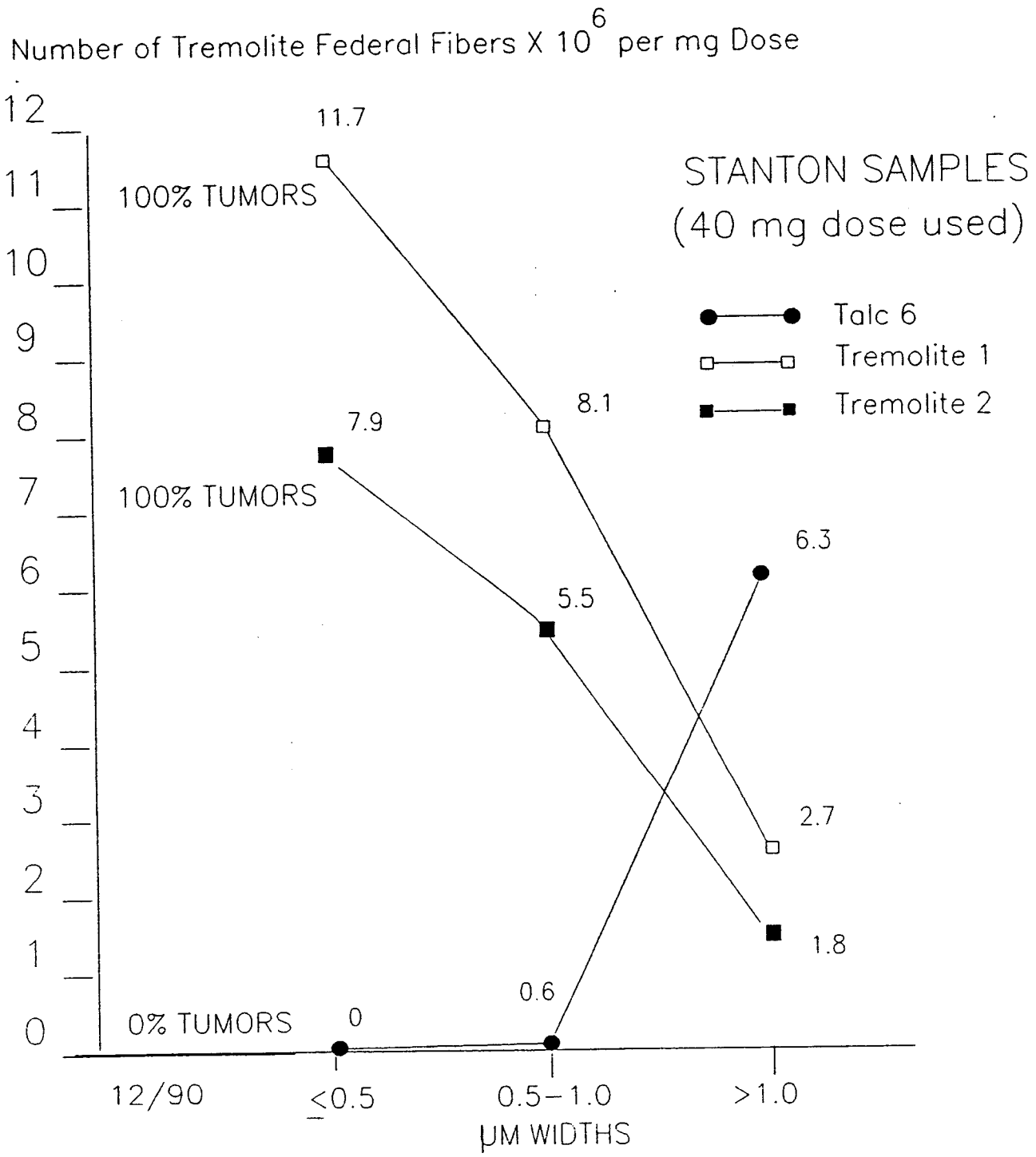
None of the tremolite particles were striated or displayed splayed ends. There is no evidence that this sample contains tremolite asbestos.

Sincerely yours,

Ann G. Wylie

Ann G. Wylie, PhD

FIGURE 9


Number of Tremolite Federal Fibers X 10^6 per mg Dose
12
11
10
9
8
7
6
5
4
3
2
1
0
11.7
100% TUMORS
8.1
7.9
100% TUMORS
6.3
5.5
2.7
1.8
0.6
0% TUMORS
0
12/90
≤0.5
0.5–1.0
>1.0
μM WIDTHS
STANTON SAMPLES
(40 mg dose used)
Talc 6
Tremolite 1
Tremolite 2

BIOLOGIC TESTS OF TREMOLITE IN HAMSTERS

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Harold J. Sobel, Eugene Marquet

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Some years ago, we began to test specially prepared samples of minerals for carcinogenicity and fibrogenicity by intrapleural injection into hamsters. In these tests, we found that we could get tumors resembling mesotheliomas by injecting preparations of chrysotile asbestos fibers, provided that we used large enough doses, and provided that we used preparations with large numbers of fibers longer than 20 μm (Smith, 1974; Smith and Hubert, 1974). From experiments with glass fibers, we learned that not only the length, but also the diameter of fibers was important, tumors resulting in hamsters after the injection of fibers 0.75 μm in diameter, but not with fibers 5 μm in diameter (Smith and Hubert, 1974).

Our long-fiber preparations of chrysotile induced extensive, fibrous pleural adhesions, and the occasional tumors came later; whereas our short fiber preparations did not. A question then arose as to whether the tumors were a non-specific result of mesothelial cells becoming trapped in fibrous pleural adhesions where their oxygen supply could be impaired, and malignant change might occur, according to Warburg's theory of carcinogenesis (Warburg, 1956).

TABLE 1. Tests of Samples of Tremolite by Intrapleural injection in Hamsters (Suspension of all samples except 72N were autoclaved before injection.)

Sample Number	Tumors/survivors[1] Dose: 25 mg			Tumors/survivors[1] Dose: 10 mg		
	350 days	500 days	600 days	350 days	500 days	600 days
14	0/35	0/27	0/20			
275	0/31	0/15	0/3[2]	0/34	0/14	0/6[3]
31	2/28	4/9	6/5	1/41	1/19	1/11
72	3/20	5/6	5/1	0/13	1/6	3/2
72N	4/22	9/10	11/2	0/25	0/19	6/9

[1]Numerator = cumulative number of hamsters with tumors related to treatment. Denominator = number survivors

[2]2 additional animals survive

[3]6 additional animals survive

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To explore that question we attempted to induce fibrosis by injecting talc, since talc had occasionally been used in surgery in attempts to induce adhesions of pleural surfaces for the treatment of pneumothorax. We bought a commercially available industrial talc, and injected that into the pleural space of hamsters. This material induced very little fibrosis, and no tumors.

The sample of industrial talc that we had used was obtained from a distributor, Whittaker, Clark & Daniels, Inc., in New York City under their label "#13 Talc", which is described by them as a fibrous talc from New York State. It became our sample FD-14, whose physical and chemical characteristics have been previously described, along with results of our biologic tests of it (Smith, 1974). It was found to contain 50% tremolite, 35% talc, 10% antigorite and 5% chlorite.

Since then, we have carried out intrapleural tests in hamsters with 3 different samples of tremolite specially prepared by various milling and separation techniques. Biologic responses to these samples have differed, as shown in Table 1.

The top line in Table 1 is data from our previously published tests of tremolitic talc (FD-14). It was tested only at our highest dose level (25 mg), and, as shown, no tumors resulted. The other samples (275, 31 and 72) listed in Table 1 are the preparations made from tremolitic ores. Sample 275 was isolated from a sample of tremolite taken from a tremolitic talc ore body similar to those from which FD-14 was produced. Sample 31 was prepared from a sample of tremolite taken from a deposit of tremolitic talc in the western United States. Sample 72 was prepared from a specimen of asbestiform tremolite.

As shown, no tumors related to treatment were found in animals injected with sample 275 at either the 25 mg or 10 mg dose level. A few animals treated with that sample are still living; however, from comparison with the other samples, it appears to be non-carcinogenic. (Animals surviving at time of presentation of this paper were subsequently necropsied. no tumors were found in them).

In contrast, tumors related to treatment were found in some animals injected with samples 31 and 72 at the 25 mg dose level, and less often, at the 10 mg dose level. The first tumor was found 184 days after injection, and most of the tumors by a year or longer after starting the tests. To compare the carcinogenicity of these samples, one must therefore bear in mind the number of animals that survived long into the period of the experiments. The number of survivors at various times, and the cumulative number of animals with tumors related to treatment are shown in Table 1. We conclude that sample 31 is less carcinogenic than sample 72. As shown, at the 10 mg dose, only a single tumor arose in response to sample 31, despite the relative number of animals that survived into late periods of the experiment. Pleural fibrosis was extensive in animals treated with sample 72, less so with 31, and very slight with 275 and FD-14. The fibrogenicity of these samples thus paralleled their carcinogenicity.

For intrapleural injection, our routine procedure has been to suspend mineral samples in saline, and sterilize the suspensions by autoclaving, before injection. In the present work, we injected one group of hamsters with a suspension of sample 72, autoclaved in our usual manner, and we injected another group of hamsters with a suspension of sample 72 that had not been autoclaved. Table 1 shows that more tumors occurred in the group given material that had not been autoclaved, but this may not be significant because the number of survivors in these 2 groups are so different.

When the samples are compared microscopically, morphologic differences can be seen. Figure 1 shows scanning electron micrographs of each sample at x 1250. Comparative measurements of fiber size distributions in those samples are not yet

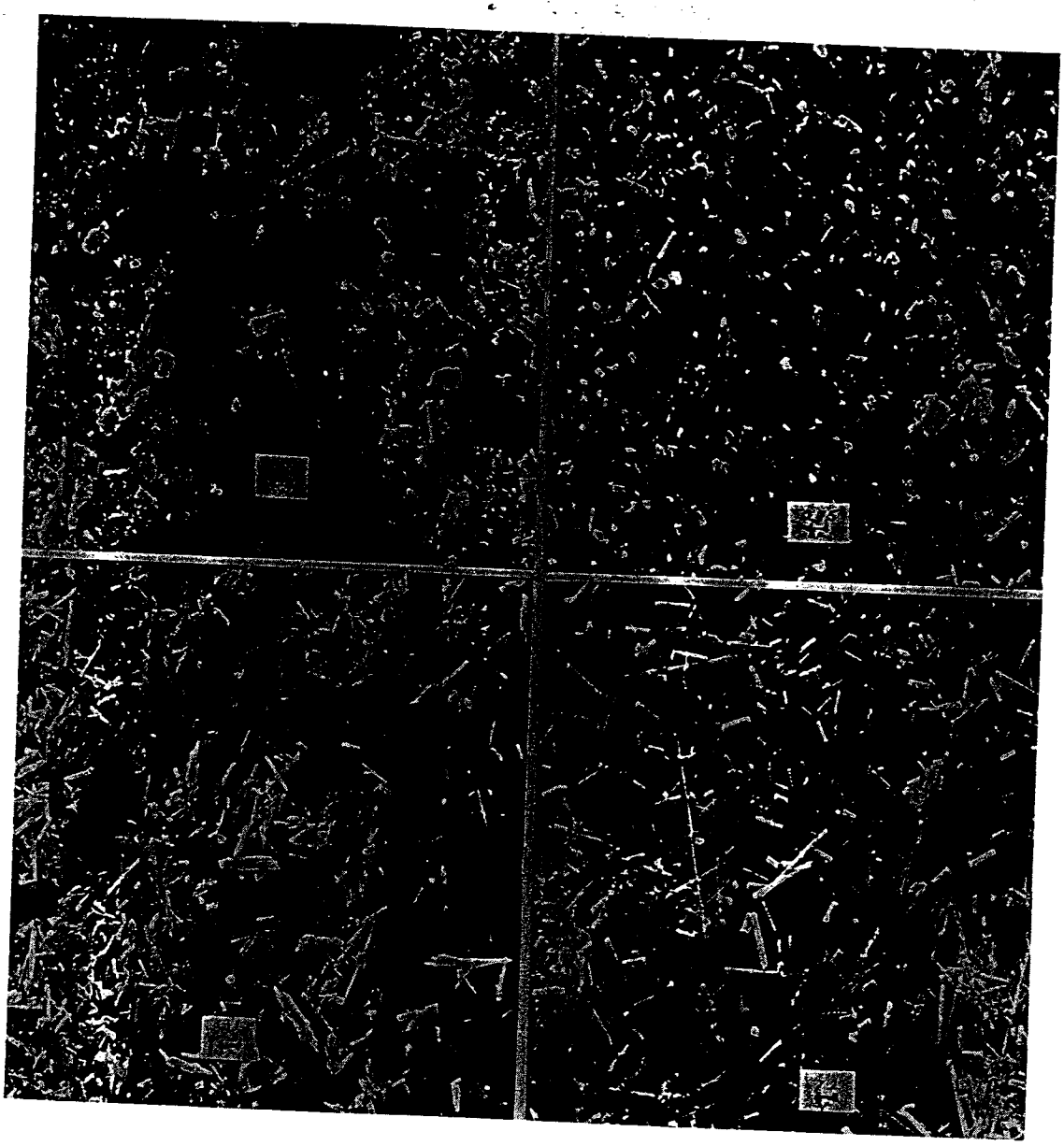

FIGURE 1. Scanning electron micrographs of samples FD-14 (upper left), 275 (upper right), 31 (lower left) and 72 (lower right). Scale on micrographs = 5 μm. Original magnification x1250.

available, but differences can be visualized from Figure 1, in which each micrograph bears a 5 μm scale.

The sample that induced most tumors (Number 72) is seen to contain numerous long, thin fibers with parallel sides. Average diameter of these fibers has been calculated as 0.4μm. By reference to the 5 μm scale on the micrograph, it can be seen that many of these fibers are longer than 20 μm.

The less carcinogenic sample (Number 31) also shows many long, thin particles. Average diameter is 0.5 μm. Some of these particles appear to have parallel sides, but others, although elongated, appear to be rather roughly shaped, resembling acicular fragments rather than crystalline fibers.

Sample 275, which induced no tumors, shows the paucity of long, thin particles so evident in samples 31 and 72. The average diameter of particles in 275 is 0.4 μm. In sample 31, as in 275, some of the elongated particles appear to be fibrous-shaped with parallel sides, but others are rather roughly shaped acicular fragments.

The other sample that proved non-carcinogenic, FD-14, shows long fibers, some thin and some thick, and many platy or amorphous particles. Recall that it contains about 35 % talc. measurements of only the fibrous-shaped particles by optical microscopy at x1000 were earlier reported to show an average diameter of 1.6 μm (Smith, 1974). Measurements of fibrous-shaped particles in the presently available scanning electron micrographs at x1250 show an average diameter of 1 μm.

The negative results with FD-14 may be explained by its lesser content of tremolite, which was 50%, although a relatively low content of tremolite would not explain the negative results with 275. X-ray diffraction studies of 275, 31 and 72 show their tremolite content to be, respectively, about 95%, 90% and 95%.

To what can we attribute the positive results with 72 and 31? Since they contain at least 5% of material other than tremolite, we cannot be sure that their activity is due wholly, or even in part, to tremolite. If we assume that their activity is due to tremolite, then the experiments indicate that appropriately high doses of long, thin particles of tremolite induced tumors, whereas high doses of shorter particles did not. This would, of course, be consistent with previous findings by ourselves and others with other materials, such as chrysotile and glass fibers.

From the point of view of industrial hygiene, it is noteworthy that the experiments show clear-cut, dose-related responses to both preparations that induced tumors. In addition, for estimation of biologic activity of materials containing tremolite, the experiments show that consideration must be given, not merely to the amount of tremolite, but also to other factors, such as the morphologic characteristics of the mineral. Factors of host susceptibility must also be considered. Most tumors in these experiments were diagnosed as mesotheliomas, of which some were examined by electron microscopy and found to contain Type C virus particles (Sobel *et al.*, 1978). Observation of virus particles in the cells of these tumors suggests further work to learn whether a virus is involved in the causation of mesotheliomas.

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Mineralogical Features Associated with Cytotoxic and Proliferative Effects of Fibrous Talc and Asbestos on Rodent Tracheal Epithelial and Pleural Mesothelial Cells

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Inhalation of asbestos fibers causes cell damage and increases in cell proliferation in various cell types of the lung and pleura *in vivo*. By using a colony-forming efficiency (CFE) assay, the cytotoxicity and proliferative potential of three mineral samples containing various proportions of fibrous talc were compared to NIEHS samples of crocidolite and chrysotile asbestos in cell types giving rise to tracheobronchial carcinomas, i.e., hamster tracheal epithelial (HTE) cells, and mesotheliomas, i.e., rat pleural mesothelial (RPM) cells. Characterization of mineralogical composition, surface area, and size distributions as well as proportions of fibers in all mineral samples allowed examination of data by various dose parameters including equal weight concentrations, numbers of fibers >5 μm in length, and equivalent surface areas. Exposure to samples of asbestos caused increased numbers of colonies of HTE cells, an indication of proliferative potential, but fibrous talc did not. RPMs did not exhibit increased CFE in response to either asbestos or talc samples. Decreased numbers of colonies, an indication of cytotoxicity, were observed in both cell types and were more striking at lower weight concentrations of asbestos in comparison to talc samples. However, all samples of fibrous minerals produced comparable dose–response effects when dose was measured as numbers of fibers greater than 5 μm or surface area. The unique proliferative response of HTE cells to asbestos could not be explained by differences in fiber dimensions or surface areas, indicating an important role of mineralogical composition rather than size of fibers. © 1997 Academic Press

Occupational exposures to mineral fibers such as asbestos are associated with the development of pulmonary and pleural disease (Mossman and Gee, 1989; Mossman *et al.*, 1990; Guthrie and Mossman, 1993). Although various types of asbestos are biologically active in a number of *in vivo* and *in vitro* bioassays, the properties of fibers important in reactivity with cells and tissues are unclear (Guthrie and Mossman, 1993; Mossman and Begin, 1989). It is generally agreed that length and width or aspect ratio are important variables for predicting the carcinogenicity and fibrogenicity of durable fibers (Davis *et al.*, 1986; Stanton *et al.*, 1981). However, the mineralogical composition and structural features of fibers and particles may also play a role in pathogenicity (Oehlert, 1991; Wylie *et al.*, 1987; Skinner *et al.*, 1988; Wylie *et al.*, 1993). These properties govern surface properties as well as durability of fibers in the lungs and pleura, factors that may be critical in the development of lung cancer and mesothelioma. (Mossman and Gee, 1989; Mossman *et al.*, 1990; Guthrie and Mossman, 1993; Health Effects Institute, 1991).

Asbestos types, in contrast to a number of other fibrous and nonfibrous nonpathogenic materials, cause both cell proliferation and cytotoxicity in a dose-related fashion in several cell types (reviewed in Health Effects Institute, 1991). These biological responses may reflect the disease potential of various fiber types, as cell injury and hyperplasia are early events in rodent inhalation models of asbestosis and carcinogenesis (Mossman and Gee, 1989; Mossman *et al.*, 1990; Guthrie and Mossman, 1993; Health Effects Institute, 1991). In this study, we compared the cytotoxicity and proliferative potential of three New York talc samples to crocidolite and chrysotile asbestos in cell types affected in asbestos-induced tumors, i.e., hamster tracheal epithelial (HTE) cells, which can give rise to tracheobronchial neoplasms, and rat pleural mesothelial (RPM) cells, cells affected in the development of mesothelioma. In studies here, we used an established colony-forming efficiency (CFE) assay that documents both increases in cell proliferation and cell survival, as measured by increases in numbers of colonies, at low concentrations of minerals, and growth inhibition, as indicated by decreases in colony formation or size at high concentration of minerals, to compare responses to well-characterized samples of asbestos and fibrous talc in HTE and RPM cells. An additional advantage of this bioassay is that it employs cells from the lung and pleura and measures responses

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to minerals over a 7-day time period of exposure as opposed to shorter time frames used (<24 hr) in most other *in vitro* assays in the literature (reviewed in Health Effects Institute, 1991. In the CFE assay, nonfibrous particles such as glass beads are proliferative or cytotoxic to HTE cells at ≥100-fold concentrations when compared to asbestos at equal weight concentrations (Mossman and Sesko, 1990; Marsh *et al.*, 1994; Timblin *et al.*, 1995).

The three talc samples used here differ somewhat in their mineralogy, both in the types of minerals and in their relative abundances. However, all three contain varying proportions of fibrous talc which is similar dimensionally and morphologically to asbestos. We thus hypothesized that factors other than length and width of fibers would govern the reactivity of minerals in the *in vitro* assays used here. The experiments were undertaken to explore the questions: (1) Do fibrous talc and asbestos fibers cause similar biological responses in epithelial and mesothelial cells? (2) Is reactivity to mineral samples dose related? and (3) Are responses in various cell types related only to numbers and sizes of fibers in each preparation or does mineralogy, including chemical composition, surface properties, and mineral structure, play a role?

METHODS

Sources of Mineral Samples

Three samples from the New York State Gouverneur Mining District, FD14, S157, and CPS183, and two asbestos samples, NIEHS chrysotile (Plastibest 20) and NIEHS crocidolite, were used in this study. The asbestos samples are essentially monomineralic and have been studied in detail (Campbell *et al.*, 1980). The general geology and mineralogy of the Gouverneur District are described by Engle (1962) and Ross *et al.* (1968). FD14 is a commercial talc, S157 was once produced from this district as a fiber talc product, and CPS183 is a laboratory separated concentrate of fibrous talc. Fibrous talc is a general term that includes fibers composed entirely of the mineral talc as well as fibers that are composed of both talc and amphibole (probably anthophyllite) intergrown on a submicrometer scale (Stemple and Brindley, 1960; Virta, 1985). The index of refraction of the fibers increases as the amphibole component increases (Veblen and Wylie, 1993). Fibrous talc is present in trace amounts in many commercial talc deposits, but it is a major component of most talc products from the Gouverneur Talc District. All samples were characterized by scanning electron microscopy (SEM), optical microscopy (OM), and x-ray diffraction (XRD); CPS183 and NIEHS crocidolite were also studied by TEM as this technique is more sensitive for the detection of smaller, thinner particles.

Characterization of Minerals

The samples were studied by XRD and SEM at Yale University in order to establish the overall mineralogy, mineral abundances, and the number of fibers per microgram. They were examined by OM at the Laboratory for Mineral Deposits Research, University of Maryland, in order to determine the mineralogy, mineral abundances, and number of fibers per microgram of the samples, and by transmission electron microscopy (TEM) at AMA Laboratories, Beltsville, Maryland (under the direction of the Laboratory for Mineral Deposits Research) for the purpose of determining the detailed size distribution of fibrous talc and especially to examine the content of fibers 0.1 μm in width and smaller. The protocols followed in each laboratory are described below. For purposes of this paper, "particles" refers to particles of all aspect ratios. "Fiber" refers to particles that have an aspect ratio (length/width) of at least five and to bundles of such fibers. "Fibers" (unless otherwise specified) include true mineral fibers (very high aspect ratio particles whose shapes were attained during mineral formation) as well as elongated cleavage fragments (shape produced during comminution).

X-ray diffraction. Samples mixed with an internal standard and spun to minimize preferred orientation were analyzed by using a SCITAG Pad V automated diffractometer. Identification of minerals was based on comparison of the X-ray pattern with standard patterns.

Optical microscopy. A known weight of sample was dispersed in water and then passed through a 22-gauge needle 8× and sonicated 4 min before mounting on slides. A drop of immersion oil $n_D = 1.598$ was placed over the dried sample. For all samples except chrysotile ($N = 2$ mixtures), at least five separate mixtures were prepared from each sample and at least two slides were made from each mixture. One-hundred fibers were counted from each slide. All fibers longer than 5 μm and all particles that appeared to be composed of bundles of fibers were categorized by length and width and by index of refraction according to the following characteristics: all indices of refraction greater than 1.598 (amphibole), index of refraction parallel to elongation greater than 1.598 and index of refraction perpendicular to elongation less than 1.598 (fibers composed of talc and a significant amount of amphibole, and referred to as talc/amphibole), or all indices of refraction less than 1.598 (fibers dominated by the mineral talc). The number of fiber per microgram was calculated by assuming that particle distributions were representative and directly proportional to the area of the filter.

Scanning electron microscopy. A known weight of sample was dispersed in water, passed through a 22-gauge syringe needle 8×, and deposited onto a 0.45-μm cellulose filter. Replicate preparations were made for each sample and analyzed independently to test for homogeneity. The filters were examined with a JEOL JXA 8600 SEM equipped with EDXA. Particles that were at least 1 μm in length and 0.12 μm in width could be detected. Mineral identification was automated by predetermining the relative percentages of Na, Ca, K, Mg, Al, Si, Mn, and Fe in mineral standards and comparing them to the elemental compositions determined on the sample particles (Petruk and Skinner, 1997). The number of particles per microgram of sample was calculated by assuming that the particle distributions were representative and directly proportional to the area of the filter.

Transmission electron microscopy. A known weight of sample was dispersed in water, flushed with a 22-gauge syringe needle 8×, and then sonicated for 4 min. The solutions were then diluted and filtered through a 0.22-μm cellulose acetate filter. The samples were analyzed on a JEOL 100 CX II electron microscope at 19,000× magnification. Over 300 fibers from each sample were measured.

Surface area measurements. All five samples were tested for single point N_2-BET surface areas by J. W. Anderson of R. T. Vanderbilt Corporation. The tests were repeated 4× for each sample. Data were expressed as square millimeters per gram of sample.

Cell culture and addition of fibers to bioassay. A HTE cell line previously isolated and characterized by Mossman *et al.* (1980) was maintained at passages from 38 to 50 and cultured routinely in Ham's F12 medium (Gibco, Grand Island, NY) containing penicillin and streptomycin (both at 100 U/ml) and 10% newborn calf serum (Gibco). This cell line is diploid and possesses features, i.e., mucin secretion and cilia, of differentiated epithelial cells. Primary cultures of RPM cells were isolated by scraping the parietal pleural of two weanling male Fischer 344 rats (Janssen *et al.*, 1994) and were maintained for up to eight passages in Ham's F12–DMEM containing antibiotics (as above), 10% fetal calf serum (Gibco), hydrocortisone (100 ng/ml), insulin (2.5 μg/ml), transferrin (2.5 μg/ml), and selenium (2.5 ng/ml).

Mineral samples presterilized in a dry oven overnight at 130°C were added to Hanks' balanced salt solution (HBSS) before titration 8× through a 22-gauge syringe needle and addition to cultures in 2% serum-containing medium.

A CFE assay was also used as a sensitive test for cytotoxicity and cell proliferation (Mossman and Sesko, 1990; Marsh *et al.*, 1994; Timblin *et al.*, 1995). HTE (400 cells/60 mm dish) and RPM (2000/60 mm dish) were plated for 24 hr before addition of dusts to medium containing 2% serum as described

TABLE 1
Characterization of Talc and Asbestos Samples

Sample	Mineralogy (% of sample)
	Mineral composition
FD14	Talc (37), tremolite (35), serpentine (15), other (<2), unknown (12)[a]
S157	Talc (60), tremolite (12), unknown (21), other (4), anthophyllite (3), quartz (1)
CPS183	Talc (50), quartz (12), unknown (28), tremolite (4), other (4), anthophyllite (3)
NIEHS crocidolite	Riebeckite (100)
NIEHS chrysotile	Chrysotile (100)
	Mineralogy of fibers >5 μm
FD14	Talc (62), amphibole (24),[b] talc/amphibole (14)
S157	Talc (84), amphibole (11), talc/amphibole (5)
CPS183	Talc (99), amphibole (1), talc/amphibole (<1)
NIEHS crocidolite	Crocidolite (100)
NIEHS chrysotile	Chrysotile (100)

Sample	Surface area (mm^2/gm)	Fibers/μg	Fibers ≥ 5 μm/μg
	Surface area and fibers/μg[c]		
FD14	6.2 ± 0.2[d]	2.5×10^3	0.8×10^3
S157	4.9 ± 0.2	1.1×10^4	4.8×10^3
CPS183	4.9 ± 0.4	1.1×10^4	9.2×10^3
NIEHS crocidolite	10.3 ± 1.3	5.3×10^5	3.8×10^5
NIEHS chrysotile	25.4 ± 0.5	5.3×10^4	3.4×10^4

[a] Primarily magnesium silicates (talc and talc/amphibole) with SEM/EDXA spectra too low for conclusive identification.

[b] The most abundant amphibole is tremolite. A very small amount of anthophyllite may be included.

[c] Data are based on SEM measurements. Chrysotile values are low due to its poor visibility on the SEM. Standard error of measurement is estimated to be 20%.

[d] Mean ± standard error of measurement of four individual measurements per group.

above. Minerals were then added, and untreated and mineral-exposed cultures were maintained for 7 days before examination. At this time, plates were rinsed in HBSS and fixed in methanol and stained with 10% Giemsa stain, and total colonies greater than 50 cells per plate were counted by using a blind code (Mossman and Sesko, 1990; Marsh *et al.*, 1994; Timblin *et al.*, 1995). Duplicate experiments were performed for each bioassay with $N = 3$–4 dishes per group per experiment. Statistical analyses of all data were performed by using analysis of variance and trend analysis.

RESULTS

Mineralogy

The overall mineralogical composition, the mineral composition of the fibers, the number of fibers per microgram, and the surface area measurement of the samples used in our studies are given in Table 1. FD14 is composed of platy talc, true mineral fibers of talc and talc/amphibole, cleavage fragments of tremolite, platy serpentine (chrysotile absent), and trace amounts of other minerals. Fibers make up approximately 11% of the particles identified by SEM. They are mostly talc followed by amphibole cleavage fragments and talc/amphibole. S157 is composed of platy talc, true mineral fibers of talc and talc/amphibole, tremolite and anthophyllite cleavage fragments, and quartz. Fibers make up about 37% of the particles, and they are mostly talc with smaller amounts of amphibole cleavage fragments and talc/amphibole. CPS183 is composed of true mineral fibers of talc and a very small amount of talc/amphibole, cleavage fragments of tremolite and anthophyllite, and quartz. Fifty-nine percent of the particles are fibers, and they are almost all fibers of talc. The three talc samples represent a range in the amount of fiber present (both in portion of sample and in number of fibers/μg) and in the mineralogy of the fibrous portion, primarily in the content of amphibole both as a separate phase and as a component of fibrous talc. NIEHS crocidolite and NIEHS chrysotile are essentially monomineralic populations of true mineral fibers of riebeckite and chrysotile, respectively. The very small widths result in many more fibers per microgram than are found in the talc samples.

Surface Area

The specific surface areas (mm^2/g) of talc samples are smaller than asbestos samples and roughly comparable to each other. The larger surface area of FD14 compared to the other talc samples is probably due to the presence of more abundant small platy talc particles that have two almost equivalent dimensions and one that is very much smaller, producing a large surface area/mass ratio. The greater surface area of chrysotile with respect to crocidolite can be attributed to its lower density and small fibril width and perhaps in part to the straw-like structure of the chrysotile fibers if N_2 penetrates the hollow center of the chrysotile tubes. Since the surface reactivity of different minerals affects the surface adsorption of N_2, some of the variation among samples may be related to mineralogy as well.

Size Distributions of Fibers in Mineral Preparations

Figure 1 shows the frequency of length and width for all fibers in units of fibers/microgram and the frequency of width for only those fibers greater than or equal to 5 μm in length as established by SEM and OM. The abundance of narrow crocidolite fibers accounts for the fact that the NIEHS crocidolite contains more fibers per microgram than any other sample (Table 1). CPS183 and S157 are very similar in many respects. They are composed of similar numbers of fibers per microgram, but there are slightly more longer fibers and fewer long, wide fibers in CPS183. FD14 contains the smallest number of fibers per microgram and the highest proportion of the widest fibers. In general, talc fibers are narrower than amphibole cleavage fragments and the differences in the sizes of the fibers among the talc samples in part reflect the differences in the abundance of amphibole cleavage fragments vs fibrous talc. As

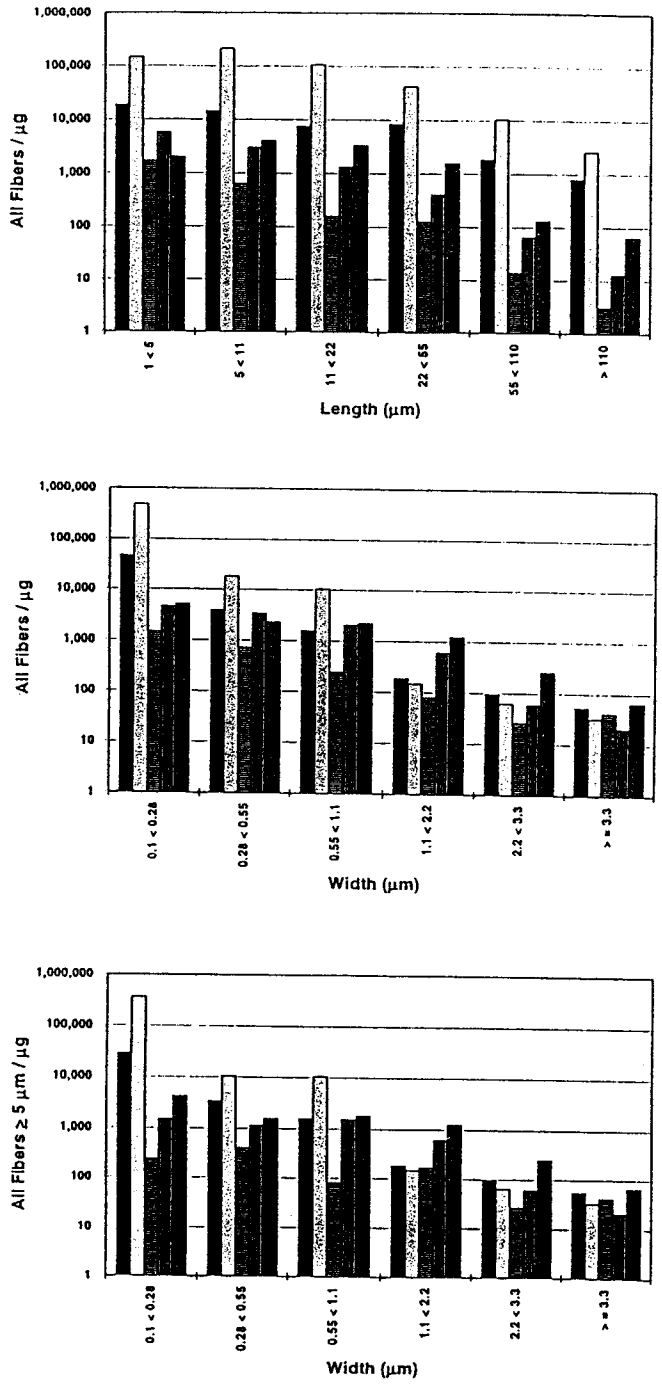

FIG. 1. The frequencies of length and width in units of fibers per microgram are shown for the three talc samples and two NIEHS asbestos samples. Also shown is the frequency of width (fibers/µg) for those fibers longer than 5 µm. (■) Chrysotile; (▤) crocidolite; (▤) FD14; (▥) S157; (▨) CPS183.

the amphibole content increases from CPS183 to S157 to FD14, the total fiber content goes down, and, on average, the fibers decrease in length and increase in width. No distinction between the size distributions of talc and talc/amphibole fibers were documented.

T2 Table 2 gives the percentage of fibers in length–width categories for CPS183 and NIEHS crocidolite asbestos as measured by TEM. These data enable a direct comparison between the dimensions of fibrous talc and crocidolite that is not restricted by the 0.1-µm width limit in the SEM data. These two true mineral fiber populations are quite similar, differing most notably in the higher proportion of wide (>0.5 µm) fibers and slightly lower proportion of long (>20 µm) fibers in fibrous talc.

CFE Assays

Combined data from duplicate experiments with HTE and RPM cells are presented in Figs. 2 and 3, respectively. CFE data F3 are expressed as a ratio of the number of colonies in mineral-exposed cultures in comparison to control colonies × 100 at various concentrations of minerals on a weight basis (µg/cm^2) as is typically found in the literature (Mossman *et al.*, 1990; Health Effects Institute, 1991). In HTE cells, both asbestos types showed an elevated number of colonies ($p < 0.05$) at lowest concentrations indicating increased cell proliferation and/or survival in response to asbestos fibers and confirming earlier studies (Mossman and Sesko, 1990; Marsh *et al.*, 1994). Significant decreases ($P < 0.05$) in CFE, an indication of toxicity or growth inhibition, were observed at concentrations of asbestos of 0.5 µg/cm^2 and greater. In contrast, RPM cells did not exhibit proliferative effects in response to either asbestos type, but statistically significant ($p < 0.05$) decreases in CFE were observed at concentrations of asbestos fibers greater than 0.05 µg/cm^2. In both cell types, the talc samples were less cytotoxic than asbestos. CPS183 was the most toxic talc sample, followed by S157 and FD14. In contrast to the other mineral samples, S157 and FD14 did not exhibit significant linear trends in cytotoxicity with increasing dosages in HTE cells.

Figures 4 and 5 show the same cellular response data as F4-F5 Figs. 2 and 3, but dose is calculated based on the number of

TABLE 2
Percentage of Fibers by Length and Width (µm) as Determined by Transmission Electron Microscopy

Length	Width: 0.01–0.1	>0.1–0.25	>0.25–0.5	>0.5–1.0	>1.0
CPS183					
<1	2.9	1.6	—	—	—
>1–2	4.1	14.1	0.5	—	—
>2–5	2.5	22.0	6.8	1.6	—
>5–10	0.9	9.8	4.3	4.5	0.5
>10–20	0.5	7.3	3.2	2.3	2.5
>20–50	0.2	1.8	2.7	1.4	2.0
>50–100	—	—	—	—	0.2
		NIEHS crocidolite			
<1	0.3	0.3	—	—	—
>1–2	1.1	9.5	0.3	—	—
>2–5	4.6	31.6	2.9	—	—
>5–10	1.4	18.1	3.7	0.6	—
>10–20	1.7	10.7	3.2	0.3	—
>20–50	0.6	2.9	1.4	1.1	—
>50–100	—	1.7	1.4	0.6	—

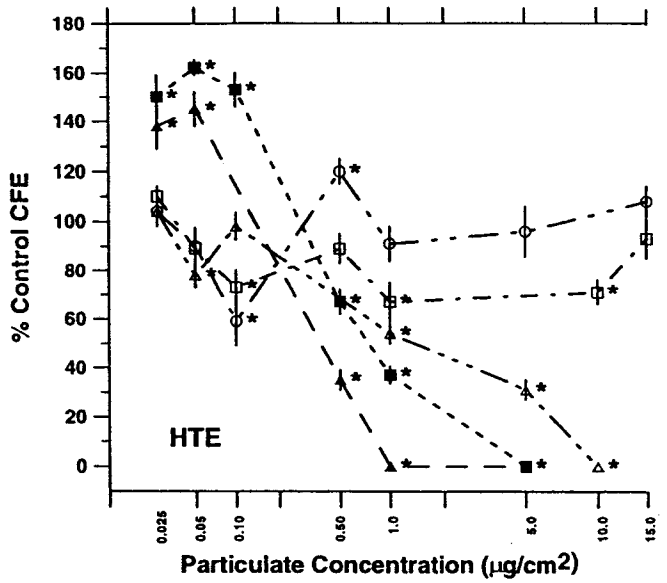

FIG. 2. Colony-forming efficiency (CFE) of HTE cells at various weight concentrations of samples. Standard error in CFE is indicated on symbol. *$p <$ 0.05 in comparison to untreated controls. (▲) Chrysotile; (■) crocidolite; (○) FD14; (□) S157; (△) CPS183.

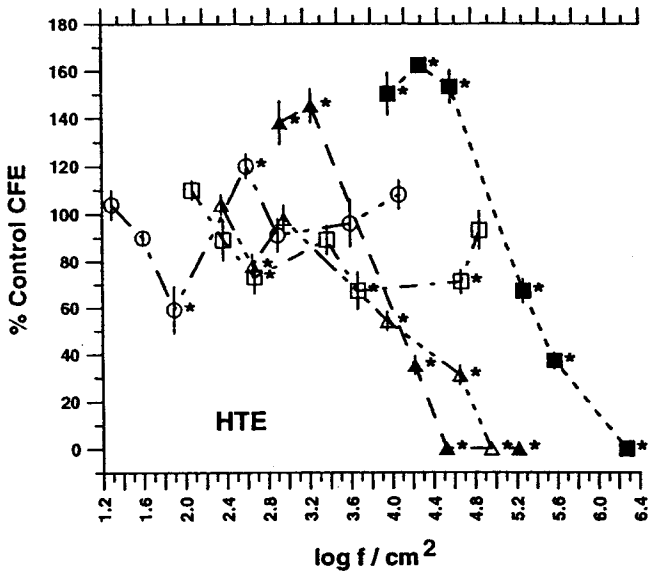

FIG. 4. Colony-forming efficiency (CFE) assays in HTE cells expressed as a function of fibers ≥5 μm in length per cm^2 (f/cm^2). The symbol width is equal to or greater than estimated error. The standard error in CFE is indicated on the symbols. *$p < 0.05$ in comparison to untreated controls. (▲) Chrysotile; (■) crocidolite; (○) FD14; (□) S157; (△) CPS183.

fibers greater than or equal to 5 μm/cm^2 (fibers/cm^2) rather than total sample weight per square centimeter. The data are taken from the SEM characterizations, but the comparisons would be the same if OM or TEM data were used. Doses of total sample per square centimeter administered to the cultures covered such a wide range that there were equivalent doses of fibers per square centimeter in almost all length/width categories for all samples. Therefore, even though crocidolite and chrysotile contained many more fibers per microgram than the talc samples, the same number of fibers per centimeter were administered in low doses of asbestos and high doses of talc (μg/cm^2).

As shown in Fig. 4, the enhanced responses of HTE cells to asbestos appear to be a function of mineralogy and not fiber

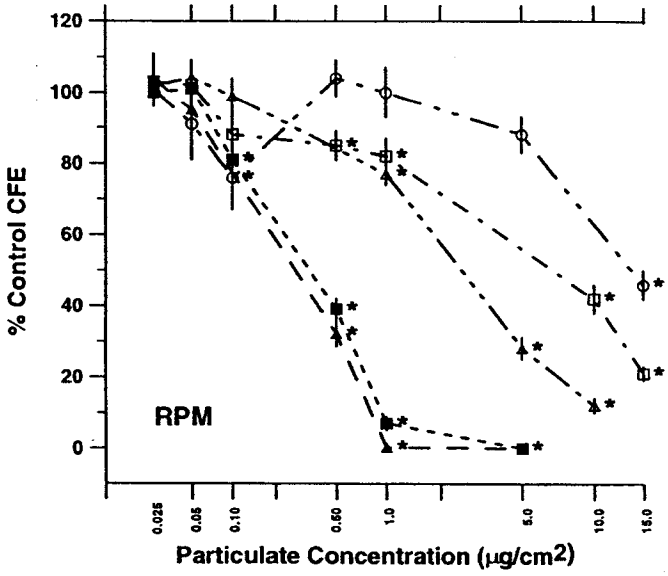

FIG. 3. Colony-forming efficiency (CFE) of RPM cells at various weight concentrations of samples. The standard error in CFE is indicated on the symbols. *$p < 0.05$ in comparison to untreated controls. (▲) Chrysotile; (■) crocidolite; (○) FD14; (□) S157; (△) CPS183.

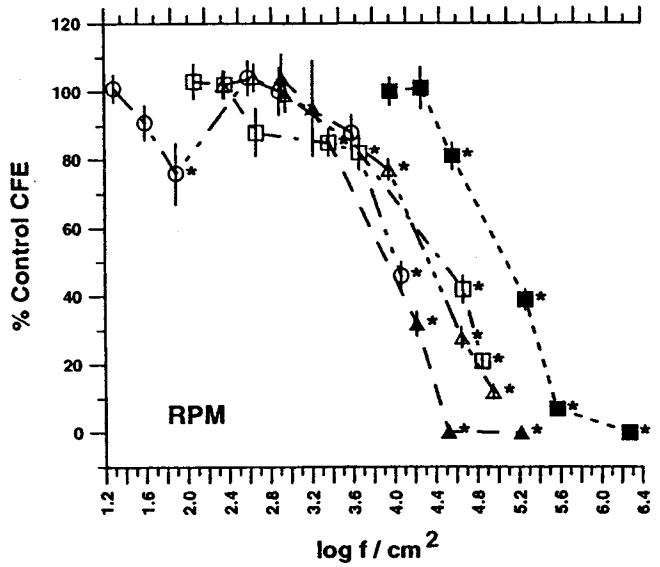

FIG. 5. Colony-forming efficiency (CFE) assays in RPM cells expressed as a function of fibers ≥5 μm in length and length:width ≥ 5:1 per cm^2 (f/cm^2). The symbol width is equal to or greater than estimated error. The standard error in CFE is indicated on the symbols. *$p < 0.05$ in comparison to untreated controls. (▲) Chrysotile; (■) crocidolite; (○) FD14; (□) S157; (△) CPS183.

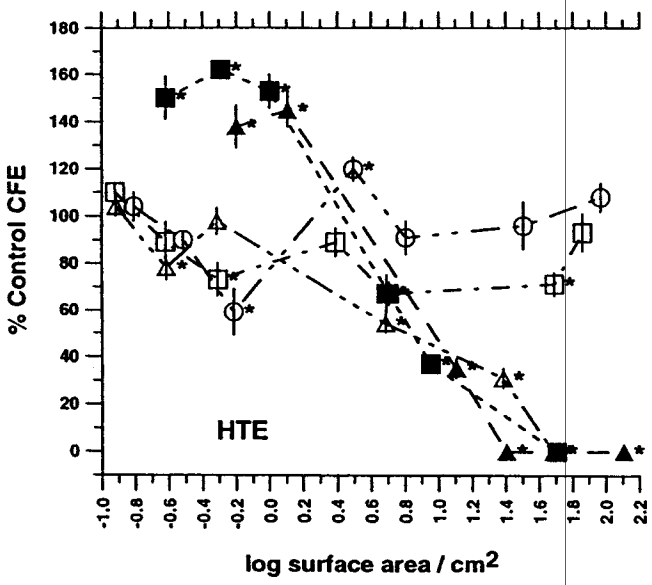

FIG. 6. Colony-forming efficiency (CFE) assays in HTE cells expressed as a function of surface areas of mineral samples (mm^2/cm^2). The symbol width is equal to or greater than one standard error. The standard error in CFE is indicated on the symbols. *$p < 0.05$ in comparison to untreated controls. (▲) Chrysotile; (■) crocidolite; (○) FD14; (□) S157; (△) CPS183.

concentration. The same concentrations of fibers greater than 5 μm of chrysotile and crocidolite that cause proliferation in HTE cells result in no effects when comparable concentrations of FD14 fibers are used, insignificant cytotoxicity with S157 fibers, and significant cytotoxicity with CPS183 fibers. It therefore seems likely that characteristics of the samples that are related to their mineralogy contribute to proliferation and/or cell growth inhibition.

As shown in Fig. 5, the response of RPM cells appears to be independent of the mineralogy of the samples. Neglecting the slight cytotoxic response of FD14 at low concentrations, the minimum concentrations of fibers per square centimeter necessary to cause significant decreases in CFE is between 10^3 and 10^4 fibers per square centimeter for all samples. In changing the size definition of a fiber (e.g., >8, ≤0.25 μm; >20 μm, all widths; all lengths, w < 0.28 μm), we found that the effective dose changed but the relationships among the samples did not (data not shown).

F6-F7 Figures 6 and 7 show CFE data in HTE and RPM cells, respectively, as a function of surface area. It is evident that surface area per se cannot explain cellular responses to minerals in HTE or RPM cells. Despite the fact that crocidolite and chrysotile have much larger surface areas per microgram, the range in the amount of sample administered resulted in similar doses between the asbestos and talc samples.

DISCUSSION

Asbestos is a term applied to a group of minerals that possess similar physical properties because of their habit of growth. However, different types of asbestos differ in their mineralogy and fiber size, which in turn may vary in preparations obtained from different geographic locations and sometimes even from the same locality (Guthrie and Mossman, 1993). The two most widely studied types of asbestos are the serpentine mineral chrysotile ($Mg_3Si_2O_5(OH)_4$), the most common type of asbestos in the Northern hemisphere and in commercial usage historically, and the asbestiform variety of the amphibole riebeckite, crocidolite ($Na_2Fe_3^{2+}Fe_2^{3+}Si_8O_{22}(OH)_2$), a high-iron-containing asbestos mined in parts of South Africa and Western Australia. Although crocidolite is implicated as more potent in the induction of mesothelioma, both chrysotile and crocidolite are linked occupationally to the development of lung cancer and asbestosis (Mossman and Gee, 1989; Mossman *et al.*, 1990, 1996; Guthrie and Mossman, 1993; Health Effects Institute, 1991).

How asbestos causes lung disease is uncertain, but acute toxicity, measured by a variety of techniques which have detected increases in membrane permeability, necrosis, release of oxygen-free radicals, exfoliation, and cell death (reviewed in Mossman and Begin, 1989) has been observed in a variety of cells exposed to high concentrations of fibers. At lower concentrations, both crocidolite and chrysotile asbestos cause cell proliferation in HTE cells and organ cultures, phenomena not observed with various synthetic fibers or nonfibrous analogs of asbestos (Marsh and Mossman, 1988; Woodworth *et al.*, 1983). These biological responses to asbestos may be important in the induction of neoplasms as cell injury may cause exfoliation and compensatory hyperplasia of surrounding cell types which are more sensitive to genetic damage. As suggested by Ames and Gold (1990), mitogenesis may facilitate mutagenesis and contribute to tumor development. In addition, cell proliferation is

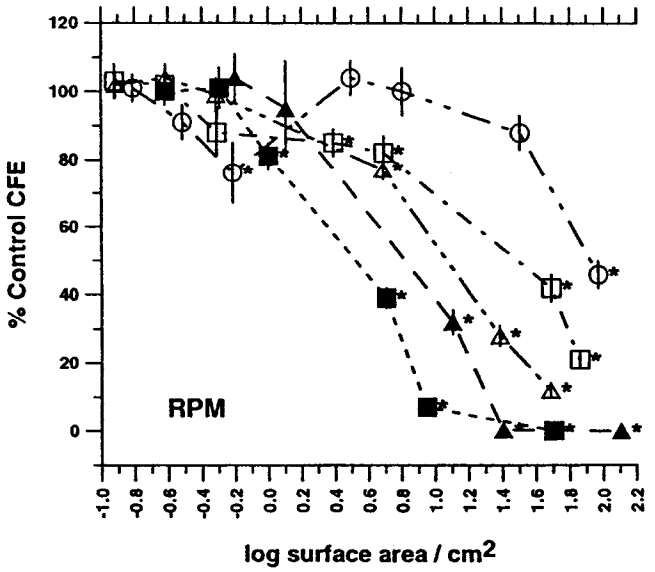

FIG. 7. Colony-forming efficiency (CFE) assays in RPM cells expressed as a function of surface areas of mineral samples (mm^2/cm^2). The symbol width is equal to or greater than one standard error. The standard error in CFE is indicated on the symbols. *$p < 0.05$ in comparison to untreated controls. (▲) Chrysotile; (■) crocidolite; (○) FD14; (□) S157; (△) CPS183.

an important component of tumor promotion and progression, and asbestos is a documented tumor promoter in epithelial cells of the respiratory tract (reviewed in Mossman *et al.*, 1990, 1996; Health Effects Institute, 1991).

Our results with asbestos samples are interesting in that HTE cells are unique in exhibiting increased CFE, in comparison to untreated and talc-exposed cells. Moreover, both cell types were more sensitive to the cytotoxic effects of equal weight dose amounts of asbestos in comparison to talc. The lack of response of RPM cells to the proliferative effects of asbestos may reflect the fact that single cells, as opposed to confluent monolayers (Marsh and Mossman, 1988; Woodworth *et al.*, 1983), were exposed to fibers here. For example, when added to confluent, growth-arrested RPM cells, crocidolite causes cell proliferation as measured by dual fluorescence techniques with an antibody to 5-bromodeoxyuridine (BrdU) and the DNA dye YOYO (Goldberg *et al.*, 1997). Moreover, increased numbers of both pleural mesothelial and bronchial epithelial cells incorporating BrdU are observed after inhalation of NIEHS crocidolite or chrysotile by rats (BeruBe *et al.*, 1996). As suggested by Gerwin *et al.* (1987), mesothelial cells may require growth factors, either produced endogenously or produced by other cell types, for proliferative responses to asbestos, and the small numbers of cells used in the CFE bioassay may not be sufficient for amounts of cytokines needed here.

Our experiments also show that fibrous talc does not cause proliferation of HTE cells or cytotoxicity equivalent to asbestos in either cell type despite the fact that talc samples contain durable mineral fibers with dimensions similar to asbestos. These results are consistent with the findings of Stanton *et al.* (1981) who found no significant increases in pleural sarcomas in rats after implantation of materials containing fibrous talc. Moreover, Smith and colleagues report no sarcomas in hamsters after implantation of FD14 (1979), and other rodent studies in which talcs of various types have been administered by inhalation of injection also have not shown an increased incidence of mesotheliomas or carcinomas (Stenback and Rowland, 1978; Wehner *et al.*, 1977). Epidemiological studies also indicate that talc in a number of occupational settings is less pathogenic than asbestos in the development of lung cancer, and the reports indicating excess lung cancer mortality may underestimate smoking habits, an important confounder, and exposure to commercial asbestos (reviewed in IARC, 1987a,b; Ross *et al.*, 1993). In essence, data have not proven that talc is a human carcinogen as small numbers of cohorts have been studied, smoking histories are poorly documented, and workers were often exposed to other dusts, including asbestos, that may cause lung disease.

Increases in cytotoxicity over time with CPS183, as opposed to the other talc samples, in both cell types also suggest the importance of mineralogic differences as the size distributions of CPS183 and S157 are similar. Since CPS183 fibers are mainly talc, while S157 contains more talc/amphibole and amphibole, mineralogical variability may affect the responses of cells to cytotoxic effects of talc. Nonfibrous particles such as quartz may also play a role in cytotoxicity of the talc samples since CPS183 higher number of quartz particles, a mineral known to be cytolytic (Mossman and Begin, 1989).

Data presented here lend increased uncertainty to the concept that long thin fibers [length >8 μm, width <0.25 μm, i.e., the Stanton hypothesis (Stanton *et al.*, 1981)] are the predominant factors predicting tumorigenicity and fibrogenicity (Mossman *et al.*, 1990; Health Effects Institute, 1991). In his elegant and comprehensive studies, Stanton and colleagues implanted two samples of fibrous talc (No. 6 and No. 7 samples) into rats. One of us (AW) examined talc No. 6 and found it to be similar in mineralogy, size distribution, and morphology to FD14, and little is known about No. 7 except that it was obtained from the Gouverneur District. Neither talc produced significant excesses in pleural sarcomas despite the fact that the dose of fibers >8 μm in length and <0.25 μm in width in sample No. 6 was large enough to predict a tumor probability of $>50\%$.

In summary, intrapleural injection studies in rats, epidemiologic investigations, and our *in vitro* work with fibrous talc here suggest caution in generalizing that durable fibers >5 μm or with aspect ratios approximating Stanton criteria are always more bioreactive and pathogenic. Our work is significant in that it supports reanalysis of the Stanton data by Wylie *et al.* (1987) and others (Oehlert, 1991; Nolan and Langer, 1993) and provides data implicating the importance of mineral type, rather than fiber length per se, in determining cellular outcomes associated with pathogenicity of mineral dusts.

ACKNOWLEDGMENTS

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CPSC Staff Report on Asbestos Fibers in Children's Crayons

August 2000

U.S. Consumer Product Safety Commission
Washington, D.C. 20207

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CPSC STAFF REPORT ON ASBESTOS FIBERS IN CHILDREN'S CRAYONS
August 2000

Summary

On May 23, 2000, the *Seattle Post-Intelligencer* reported finding asbestos in three major brands of crayons, Crayola, made by Binney and Smith; Prang, made by Dixon Ticonderoga; and Rose Art. The reported asbestos was believed to be found in the talc used by the crayon manufacturers as a binding agent. The specific asbestos minerals reported by the laboratories contracted by the Seattle Post-Intelligencer, tremolite, chrysotile, and anthophyllite, were identified in some of the crayons in concentrations ranging from 0.03% to 2.86% by transmission electron microscopy (TEM). Asbestos was not identified in any of the tests conducted by the three crayon manufacturers.

The U.S. Consumer Product Safety Commission (CPSC) staff examined crayons from several different boxes from the three companies to determine whether asbestos was present, evaluated the potential for exposure to children, and evaluated the potential risk.

Trace amounts of anthophyllite asbestos and larger amounts of other fibers (transitional fibers) were found in Crayola and Prang crayons by polarized light microscopy (PLM). The concentrations of asbestos ranged from below the limit of detection to 0.03%. The concentrations of transitional fibers ranged from below the limit of detection to 1.25%. The Rose Art crayons did not contain any asbestos or transitional fibers.

Based on the results of the testing and evaluation, the staff concludes that the risk a child would be exposed to the fibers through inhalation or ingestion of crayons containing asbestos and transitional fibers is extremely low. No fibers were found in the air during a simulation of a child vigorously coloring with a crayon for half an hour. The risk of exposure by eating crayons is also extremely low because the fibers are imbedded in the crayon wax and will pass through the child's body.

Although CPSC staff determined that the risk is extremely low, the staff believes that as a precaution, crayons should not contain these fibers. CPSC staff asked the industry to reformulate crayons using substitute ingredients. Binney and Smith and Dixon Ticonderoga agreed to reformulate within a year to eliminate talc. Rose Art indicated that they stopped using talc in 90% of their crayons about 15 months ago and will reformulate the remaining small percentage of crayons made with talc.

CPSC will continue to monitor children's crayons to ensure they do not present a hazard.

B. Air Sampling for Fibers

To determine the potential for airborne exposure to asbestiform fibers by individuals using crayons, a quantitative measure of the release of fibers during the use of crayons was investigated through simulated exposure activities in a glove bag. MCE air filters collected particles from the glove bag air during 30 minutes of using Crayola and Prang crayons on sheets of standard copying paper. The filter samples were analyzed for fibers using phase contrast microscopy by NIOSH Method 7400 (Appendix B).

III. Results

A. Crayon analysis

Neither laboratory detected any fibrous material in the samples of Rose Art crayons. No fibers were found in a white Crayola crayon or in a Crayola washable crayon. Both labs detected fibers in 16 other crayon samples from Crayola and Prang by PLM and TEM analyses. Trace amounts of asbestos and larger amounts of other fibers (transitional fibers) were found in samples of Crayola and Prang crayons. The concentrations of asbestos ranged from below the limit of detection to 0.03%. The concentrations of transitional fibers ranged from below the limit of detection to 1.25%.

B. Air sampling

No fibers other than cellulose were identified on the air filters.

IV. Discussion of Difficulties in Analysis and Conflicting Lab Results

As discussed above, asbestos refers to six specific asbestiform minerals. Some of these minerals also exist in non-asbestiform habits. When crushed, these minerals may form cleavage fragments that are fibers, but that are not asbestiform. Cleavage fragments generally have mean aspect ratios less than 10:1, while asbestiform minerals usually have mean aspect ratios greater than 20:1. Talcs can be complex mixtures of minerals. Talc may be present in a fiber form, and amphibole minerals in both the asbestiform and non-asbestiform varieties (cleavage fragments) may be present. Talc may also contain transitional (intermediate) fibers that have features that are similar to both anthophyllite and talc. Proper identification of each of these fiber types requires the use of a combination of PLM and TEM with careful analysis of the diffraction patterns and chemistry of each particle. A detailed discussion of the analysis of complex talc samples can be found in Appendix C.

Although cleavage fragments are not asbestos, the most common method used by NVLAP (National Voluntary Laboratory Accreditation Program) laboratories requires the inclusion of cleavage fragments in the asbestos fiber count. The identification of tremolite asbestos in crayons reported by the *Seattle Post-Intelligencer* is likely related to this requirement. Further, the reporting by other laboratories of greater amounts of anthophyllite asbestos than the CPSC analysis is likely due to misidentification of transitional fibers as anthophyllite fibers. The industry reported that no asbestos fibers were detected in their analyses of crayons. They did not quantify the other fibrous constituents, *i.e.*, talc fibers, transitional fibers, and cleavage fragments. Thus, although several laboratories have analyzed similar crayons, the results differ in the

AIR MONITORING SURVEY
AIRBORNE FIBER AND GENERAL PARTICULATE

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30 Winfield Street
Norwalk, CT 06855

Prepared: November 21, 2000

On November 9, 2000 an emission study was undertaken to determine the quantitative and qualitative characteristics of mineral fibers generation during hand sanding of a paint containing a high load of Vanderbilt talc. Details concerning the paint, the air monitoring and analytical protocol employed appear in the appended attachments.

An effort was made to measure the concentration in fibers/cc of all 3 to 1 aspect ratio or greater fibers longer than 5 microns. Of those fibers, elongated particulates that satisfied the mineralogic and OSHA definition of asbestiform was to be determined and similarly quantified. Total dust and respirable dust (all particles below 10 microns) were also collected.

Monitoring cassettes were fixed on both sides of the surface being sanded as indicated in the appended diagram and photos. One fiber personal sample was fixed to the lapel (breathing zone) of the sander. The surface sanded was at, just above and just below the breathing zone level. A secured plasterboard with three paint coats (different colors) was actively sanded by hand with alternating coarse and fine aluminum oxide sandpaper for one hour. Sanded particulate falling to the floor was collected and submitted for qualitative analysis.

Qualitative analysis of the settled dust was intended to evaluate the condition of a minor talc and transitional fiber component in the paint dust contrasted to similar fibers observed in the talc raw material. The talc raw material was Vanderbilt talc NYTAL 300 (grade). The weight percent of asbestiform fibers in this grade (talc fiber) had previously been determined to be 0.15% (an average weight %). The loading of this talc in the paint would be in the 35% range (higher end).

RESULTS

While both the total and respirable dust cassettes were fixed only 2 feet from the surface of the board and to the left, only a slight difference between total and respirable dust was found (0.84 mg/m^3 versus 0.73 mg/m^3 respectively). This result suggests that sanded paint particulate tends to be large and/or heavy with little carry or extended time suspension in still air. Observation of the settled paint dust does suggest a preponderance of large particles in the micrometer range. This observation is consistent with other paint sanding particulate observations and to be

expected given the encapsulation of particulates in paint pigments and binders (NPCA crystalline silica sanding study).

No fibers above the detection limit of 0.0096 fibers/cc could be found. It was therefore not possible to conduct additional analysis regarding the asbestiform nature of airborne fibers generated.

Talc and transitional fibers noted in the paint dust were reported as difficult to find and when found tended to be thicker than those noted in the raw talc products. The analytical report stated that the "fibrous minerals in the dust were encapsulated within the paint matrix". In regard to particle size, "approximately 92.7% of the material is coarser than 10 um, while 97.2% of the material is coarser than 5 um". It was noted that a few free mineral particles were observed in the paint dust but the majority of all particles were complex structures of mineral and paint matrix.

CONCLUSION

Under the conditions of this study no detectable airborne fiber emissions during the sanding of a Vanderbilt talc containing paint was found. Observation of the sanded dust shows the vast majority of all particles to be encapsulated within the paint matrix.

COMMENT

This is considered a very basic survey with a protocol adequate to approximate the potential for fiber emission during the sanding of Vanderbilt talc containing paint.

More rigorous follow-up studies are advised if additional data is desired. A more rigorous study might include expanded sampling periods, the possible use of mechanical sanders and a detailed analysis of both settled dust and airborne dust with regard to particle size distribution (pre and post paint blend). The test environment should be more carefully monitored in respect to temperature and airflow.

DATA SHEET: Paint Sanding Air Samples - November 9, 2000 - One Hour Sample Time

Sample	Liter Vol.	Location	Contaminant	Concentration Found
F-1	121.2	Fixed 2' from board - breath zone level	Fiber*	Below detection*
26503	123		Total Dust*	0.84 mg/m^3
25188	103		Resp. Dust*	0.73 mg/m^3
F-3	120.2	Left upper edge of board	Fiber	Below detection
F-2	120.2	Personal Sample - lapel of sander	Fiber	Below detection

* Fiber: Any elongated particulate with an aspect ratio of 5 to 1 or more, 5 microns or longer. Analysis by R. J. Lee, Inc. (AIHA & NVLAP accredited) - fiber analysis by PCM, SEM, TEM as required. Monitoring protocol applied: NIOSH 7400 method.

* Detection Limit: 0.0096 fibers/cc

* Total Dust: Hartford Lab. Ref.# 16688 - Particulate by gravimetry NIOSH 0500

* Respirable Dust: All particles below 10 microns in size. Hartford Lab. Ref. #16688 - Particle by gravimetry NIOSH 0500

VENTILATION

Corner of laboratory room, no air movement (smoke tube emission showed little drift)

MATERIALS

Sandpaper: 3M 366u aluminum oxide resin paper - 60 coarse; 150 fine.

Paint: (see label)
Base coat = Gray, non-NYTAL latex primer
Prime coat = White, Glidden Stain Jammer - NYTAL 300 loading
Top coat = Green tinted Glidden Stain Jammer - NYTAL 300 loading
The loading of talc in this type of flat primer is typically 30 to 40% (upper end of loading %)

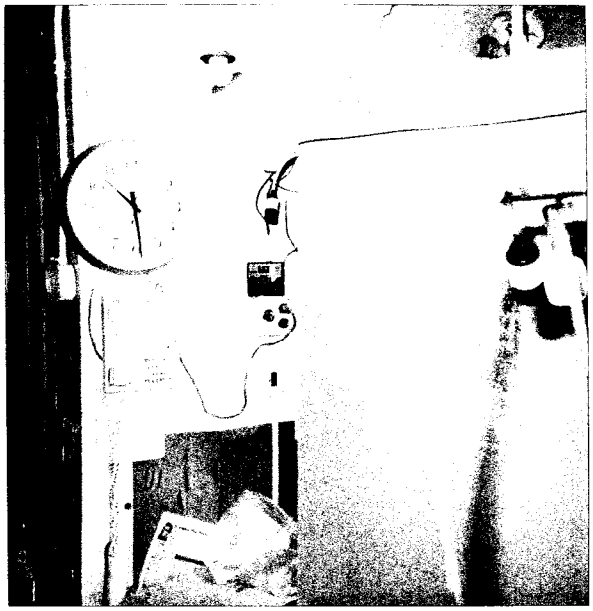
Calibration Record
November 9, 2000

Pump # (filter #)	Desired Flow Rate Liters/min	Lpm Avg. 3 Rates Prior	Lpm Avg. 3 Rates After	Difference	Lpm Flow Rate	Run Time (minutes)	Air Volume Liters	Initial
RT-1	2.0	2.01	2.04	0.03	2.02	60	121.2	
(F-1)								
RT-3	2.0	2.003	2.005	0.002	2.004	60	120.2	
(F-2)								
DCC-2	2.0	2.003	2.006	0.003	2.004	60	120.2	
(F-3)								
825	1.7	1.708	1.725	0.018	1.717	60	103.02	
(25188)								
B-1	2.0	2.04	2.06	0.02	2.05	60	123.0	
(26503)								

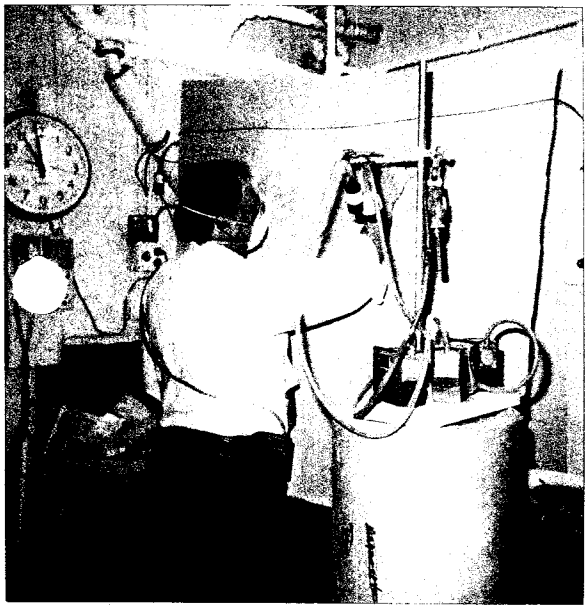
Calibrator: The Gilibrator PN#800268 Primary Flow Calibrator Flow cell assay (std). Range 20 cc - 6 lpm Gilian Instrument Corp. Last Factory Calibration: 2/00

Pumps: Gil Air Personal Air Sample - Gilian Instrument Corp.

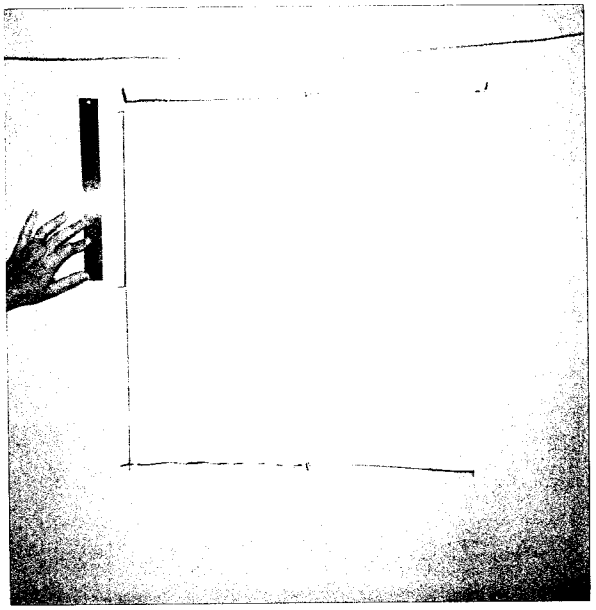
Start



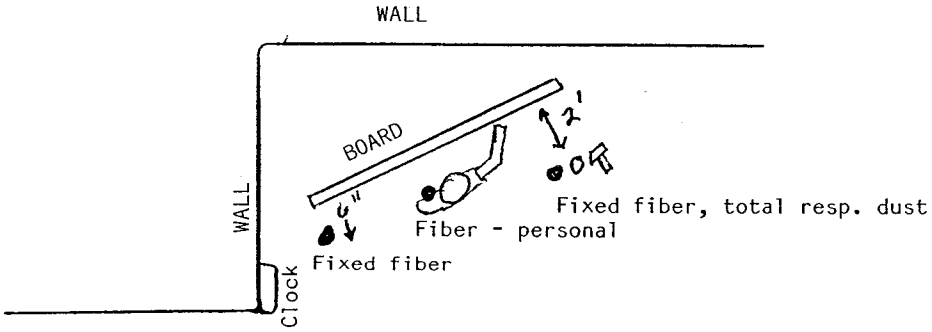
Area sanded after 30 minutes.



End



60 minutes of active sanding resulted in approximately 4 square feet of top and primer coat removal.



Monitoring Positions
Breathing Zone Height

ASSURED SATISFACTION LIMITED WARRANTY

dden/ICI Paints warrants satisfaction en applied according to label instructions. not satisfied as warranted, return the used portion along with sales receipt place of purchase. We will refund the ce paid for the product or replace with oduct of equal value. **THIS WARRANTY SPECIFICALLY EXCLUDES LABOR OR COST OF LABOR FOR THE APPLICATION OF ANY PAINT.** Some states do not allow the exclusion of incidental or consequential damages, so the limitation of exclusion contained in the above warranty may not apply to you. This warranty gives you s ecific legal rights, and you may also have o her rights which vary from state to state.

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MAXIMUM VOC 450 GPL (3.75 LBS/GAL)

Ultra-Hide® Stain Jammer Primer-Sealer

A premium quality, fast drying stain killer and general purpose primer for new and previously painted interior wood, drywall or metal surfaces. Excellent as a st n killer for water stains, lipstick, smoke, ink, crayons and knots or soap streaks on walls, trim and ceilings. Stain JAMMER also has tenacious adhesion to many hard-to-paint surfaces. Provides fast recoat time and is sandable in 45 minutes, making it ideal for new home construction and remodeling. Also recommended as a primer for drywall which is to receive vinyl wallcovering. May be used under latex, oil or alkyd topcoats. Not recommended over plaster or large expanses of exterior wood surfaces.

GENERAL SURFACE PREPARATION: All surfaces must be sound, dry, clean and free of oil, grease, dirt, mildew, form release agents, curing compounds, loose and flaking paint and other foreign substances. Wash stains with detergent, rinse clean and dry before painting.
NEW SURFACES: Wood - Countersink nails. Fill holes, cracks and joints with a latex spackle or filler. Sand smooth and dust clean. Prime with this paint. **Drywall** - Prime with this paint. **Steel** - Prime with this paint, solventborne metal primer. **Galvanized Metal and Aluminum** - Prime galvanized metal with solventborne metal primer. Prime aluminum with this paint or solventborne metal primer.
PREVIOUSLY PAINTED SURFACES: Wash to remove contaminants. Rinse thoroughly with water and allow to dry. Dull glossy areas by light sanding. Remove sanding dust. Remove loose paint. Prime bare areas with primer specified under NEW SURFACES.
TINTING: May be tinted with up to two oz/gal of universal colorants.

APPLICATION: May be applied by brush, roller or spray. No th ning required. For airless spray use a .015" tip. Adjust pressure as needed. Do not a ply when surface or air temperature is below or expected to be below 40°F (4°C). Pro de good ventilation and wa th for normal drying.
SPREADING RATE: Mix thoroughly before use. Apply at 400 s ft/gal (10 m²/L). Actual cove age may vary depending on substrate and application metho.
DRYING TIME: At 77°F (25°C) and 50% R.H., dries to touch in 30 minutes and to recoat in one hour. Low temperature, high humidity, thick films or poor ventilation will increase these times.
CLEAN-UP: Clean immediately with mineral spirits.

L.C. 997090

ANALYSIS
Castor Oil Derivative (CAS Unknown)
Vinyl Toluene Alkyd Copolymer (CAS Unknown)
Solvent Naphtha (Petroleum), Medium Aliphatic (64742-88-7)
Hexanoic Acid, 2-Ethyl-, Cobalt (2+) Salt (136-52-7)
Benzene, Ethyl- (100-41-4)
Solvent Naphtha (Petroleum), Light Aliphatic (64742-89-8)
Limestone (1317-65-3)
Quartz (14808-60-7)
Antigorite (12135-86-3)
Tremolite, Nonasbestiform (14567-73-8)
Talc (14807-96-6)
Anthophyllite, Nonasbestiform (17068-78-9)
Titanium Oxide (13463-67-7)
Contents Partially Unknown

PS20006 9960-A

DISPOSAL: Contains no chromium, lead or mercury. Place opened, empty containers in normal refuse for disposal. Contact your sanitation department or household hazardous waste coordinator for information concerning re-use, recycling or disposal of unused latex paint. 640-C1

ELIMINACION: No contiene cromo, plomo ni mercurio. Deseche los recipientes abiertos y vacíos con la basura normal. Comuníquese con el departamento sanitario o con la coordinación de desechos peligrosos caseros para obtener información acerca de la reutilización, reciclado y desecho de pinturas de látex sin usar. 640-C1

DANGER! FLAMMABLE LIQUID AND VAPOR. HARMFUL OR FATAL IF SWALLOWED. ASPIRATION HAZARD-CAN ENTER LUNGS AND CAUSE DAMAGE. HARMFUL IF INHALED. MAY CAUSE CENTRAL NERVOUS SYSTEM EFFECTS, INCLUDING DIZZINESS, HEADACHE OR NAUSEA. CAUSES EYE, SKIN, AND RESPIRATORY TRACT IRRITATION. OVEREXPOSURE MAY CAUSES LIVER, KIDNEY DAMAGE. CONTAINS CRYSTALLINE SILICA WHICH CAN CAUSE LUNG CANCER AND OTHER LUNG DAMAGE IF INHALED. WHEN TINTED, CONTAINS ETHYLENE GLYCOL WHICH CAN CAUSE SEVERE KIDNEY DAMAGE WHEN INGESTED AND HAS BEEN SHOWN TO CAUSE BIRTH DEFECTS IN LABORATORY ANIMALS. USE ONLY WITH ADEQUATE VENTILATION. KEEP OUT OF THE REACH OF CHILDREN. NOTICE: This product contains solvents. Reports have been associated repeated and prolonged occupational overexposure to solvents with permanent brain damage and nervous system damage. Intentional misuse by deliberately concentrating and inhaling the contents may be harmful or fatal. **This product contains a chemical known to the state of California to cause cancer.** For emergency information call (800) 545-2643.For additional safety information, refer to the Material Data Safety Sheet for this product. Keep away from heat, sparks, and flame. **Do not** smoke. Vapors may ignite. Extinguish all flames, burners, stoves, heaters and pilot lights and disconnect all electrical motors and appliances before use and until all vapors are gone. If sanding is done, wear a dust mask to avoid breathing of sanding dust. Do not breathe vapors or spray mist. If you experience eye watering, headaches, or dizziness, leave the area. If properly used, a respirator may offer additional protection. Obtain professional advice before using. Close container after each use. **FIRST AID:** In case of skin contact, wash off **quickly** with plenty of soap and water, remove contaminated clothing. For eye contact flush **immediately** with large amounts of water, for at least 15 minutes. **Obtain emergency medical treatment.** If swallowed, **obtain medical treatment immediately.** If inhalation causes physical discomfort, remove to fresh air. If discomfort persists or any breathing difficulty occurs, **get medical help.** CCPL485-0699

¡PELIGRO! LIQUIDO Y VAPOR INFLAMABLES. DAÑINO O FATAL SI SE TRAGA. PELIGROSO SI SE ASPIRA-PUEDE PENETRAR EN LOS PULMONES Y CAUSAR DAÑO. DAÑINO SI SE INHALA. PUEDE CAUSAR EFECTOS EN EL SISTEMA NERVIOSO CENTRAL. INCLUYENDO MAREOS, DOLOR DE CABEZA O NAUSEAS. CAUSA IRRITACION DE OJOS, PIEL Y TRACTO RESPIRATORIO. LA SOBREEXPOSICION PUEDE CAUSAR DAÑO AL HIGADO Y RIÑONES. CONTIENE SILICE CRISTALINO QUE PUEDE CAUSAR CANCER DE PULMON Y OTROS DAÑOS PULMONARES SI SE INHALA. CUANDO VIENE TENIDO, CONTIENE ETILENGLICOL QUE PUEDE CAUSAR DAÑO SEVERO A LOS RIÑONES CUANDO SE INGIERE Y SE HA MOSTRADO QUE CAUSA DEFECTOS DE NACIMIENTO EN ANIMALES DE LABORATORIO. USELO SOLAMENTE CON VENTILACION ADECUADA. MANTENGALO LEJOS DEL ALCANCE DE LOS NIÑOS. AVISO: Este producto contiene solventes. Hay informes que han asociado la sobreexposición a solventes repetida y prolongada por motivos laborales con daño permanente al cerebro y al sistema nervioso. El mal uso intencional en concentrar e inhalar deliberadamente el contenido puede ser dañino o fatal. **Este producto contiene un compuesto químico que según el estado de California causa cáncer.** Para obtener información de emergencia, llame al (800) 545-2643. Para obtener información adicional de seguridad, consulte la Hoja de Datos sobre Seguridad de los Materiales para este producto. Manténga alejado del calor, chispas y llamas. **No** fume. Los vapores pueden encenderse. Apague todas las llamas, quemadores, estufas, calentadores y flamas pilotos y desconecte todos los motores y aparatos léctricos antes de usar el producto y hasta que los vapores se hayan disipado. En caso de lijar, utilice una mascarilla para evitar respirar el polvo resultante. No respire los vapores ni la neblina del espray. En caso de lagrimeo, dolores de cabeza o mareos, abandone el área. El empleo de un respirador puede ofrecer una protección adicional si se usa de manera apropriada. Antes de usarlo consulte con un especialista. Cierre el envase después de usar. **PRIMEROS AUXILIOS:** En caso de contacto con la piel, quítelo **rápidamente** con abundante agua y jabón, quítese la ropa contaminada. En caso de contacto con los ojos, enjuáguese **inmediatamente** con abundante agua por lo menos durante 15 minutos. **Obtenga tratamiento médico de emergencia.** Si se traga, **obtenga tratamiento médico inmediatamente.** Si la inhalación provoca malestar físico, lleve a la persona afectada al aire libre. Si las molestias persisten o si se presentan dificultades para respirar, **obtenga asistencia médica.** CCPL485-0699

ICI **Paints** *World Leader*

Glidden **The Glidden Company**
Cleveland, Ohio 44115

The Glidden Company is a member of the ICI Paints World Group

The Hartford - Industrial Hygiene Laboratory
Hartford Plaza Hartford, CT 06115
Toll Free Phone 1-800-986-3509
Phone - (860) 547-4557 Fax - (860) 547-6302

Account:	R.T. VANDERBILT	Laboratory #:	16688
Address:	NORWALK, CT	Analyst:	GEORGE REDFORD
Submitted:	JOHN KELSE		
Date Rec'd:	11-13-00	Date Rpt'd:	11-16-00

Referenced Analytical Method: PARTICULATE BY GRAVIMETRY NIOSH 0500

Sample #	Volume (liters)	PARTICULATE Mg	Mg/M^3
LOQ's (Mg)		0.025	
26301	---	<0.025	---
25188	103	0.075	0.73
26503	123	0.103	0.84

Note:	The concentration values (e.g. mg/M^3, ppm, fibers/cc, etc.) were calculated at the laboratory using data and information (times and/or flow rates) supplied to the laboratory by the submittor.

Note:	If applicable, organic sampling tube sections are analyzed separately. "<" means not detected at the limit of quantification (the amount of this material that can reliably be reported based upon analytical conditions.

Abbreviations:	Mg = Milligrams Mg/M^3 = Milligrams per Cubic Meter of Air

Cynthia Gosselin

Ann McClure, CIH
Laboratory Manager

Cynthia Gosselin, CIH
Laboratory Supervisor

RJ Lee*Group*, Inc.

350 Hochberg Road
Monroeville, PA 15146
Tel: (724) 325-1776
Fax: (724) 733-1799

The Materials Characterization Specialists

November 22, 2000

Mr. John W. Kelse
R. T. Vanderbilt Company, Inc.
30 Winfield Street
Norwalk, CT 06856-5150

RE: Analysis of Dust from Paint Sanding
RJ Lee Group Job No.: LSH006444

Dear Mr. Kelse:

RJ Lee Group has examined a sample of dust generated during sand papering of a green paint. The sample (labeled "Sand papered paint containing NYTAL 300") was received on November 10, 2000 and assigned our sample number 3026573.

The initial examination of the sample was performed using a polarized light microscope (PLM). A portion of the sample was suspended in a several drops of 1.598 refractive index oil. During the PLM examination, a trace amount of non-asbestiform talc was observed; the majority of particles observed were opaque to the transmitted light. Thus, any fibrous minerals in the dust were encapsulated within the paint matrix.

A secondary examination of the dust was performed using computer controlled scanning electron microscopy (CCSEM). This analysis was performed to determine the mass fraction of dust coarser than 10 μm and the mass fraction coarser than 5 μm. A portion of the dust was suspended in 100 ml of distilled water. An aliquot of the suspension was deposited onto a 0.2 μm polycarbonate filter. The filter was coated with a thin film of carbon and prepared for CCSEM analysis. The data from this analysis are summarized on the attached sheet. Approximately 92.7% of the material is coarser than 10 μm, while 97.2% of the material is coarser than 5 μm.

The sample was examined using manual SEM techniques. Images of representative particles were collected and are attached as Figures 1 – 10. A few free mineral particles were observed (Figures 1 – 5), but the majority of all particles were complex structures of mineral and paint matrix (Figures 6 – 10).

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liability provisions. No responsibility or liability is assumed for the manner in which the results are used or interpreted. Unless notified in writing to return the samples covered in this report, RJ Lee Group will store the samples for a period of 30 days before discarding. A shipping and handling fee will be assessed for the return of any samples.

If you have any questions, please feel free to call me.

Sincerely,

Drew R. Van Orden, PE
Senior Scientist

Sample_Number 3026573

Mag	Fields	Grid
200	471.0000	1.736
800	75.1351	0.434

Classes	#	Number %	Area %	Vol %	Wt %	Area Fr.	Num/cm^2
Other	2141	88.20	90.53	96.20	96.92	0.0040495	5.814E+004
Tremolite	152	6.75	7.42	3.23	2.60	0.0003321	4.447E+003
Possible Talc	76	5.06	2.04	0.57	0.48	0.0000913	3.335E+003
Totals	2369	100.00	100.00	100.00	100.00	0.0044729	6.592E+004

Size Distribution by Average Diameter (microns)

			0.2 - 5.0	5.0 - 10.0	10.0 - 500.0	
Classes	Number %	<<<				>>>
Other	88.2	0.0	96.0	2.9	1.1	0.0
Tremolite	6.7	0.0	93.2	5.9	0.9	0.0
Possible Talc	5.1	0.0	98.1	1.6	0.4	0.0
Totals	100.0	0.0	95.9	3.0	1.1	0.0

Volume Distribution by Average Diameter (microns)

			0.2 - 5.0	5.0 - 10.0	10.0 - 500.0	
Classes	Volume %	<<<				>>>
Other	96.2	0.0	2.4	4.1	93.6	0.0
Tremolite	3.2	0.0	10.7	18.1	71.2	0.0
Possible Talc	0.6	0.0	21.7	18.3	60.0	0.0
Totals	100.0	0.0	2.7	4.6	92.7	0.0

Mass Distribution by Average Diameter (microns)

			0.2 - 5.0	5.0 - 10.0	10.0 - 500.0	
Classes	Mass %	<<<				>>>
Other	96.9	0.0	2.4	4.1	93.5	0.0
Tremolite	2.6	0.0	10.6	17.8	71.6	0.0
Possible Talc	0.5	0.0	21.5	18.2	60.3	0.0
Totals	100.0	0.0	2.7	4.5	92.7	0.0

RT Vanderbilt Co.
RJ Lee Group Project No. LSH006444
Sandpapered Paint (RJLG sample 3026573)

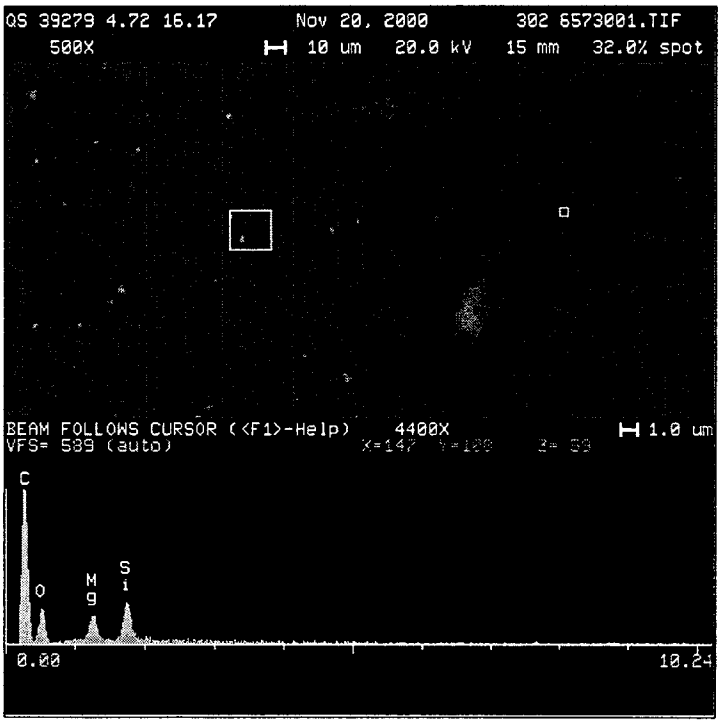

Figure 1. Backscattered electron image with EDS spectrum of fibrous talc particle.

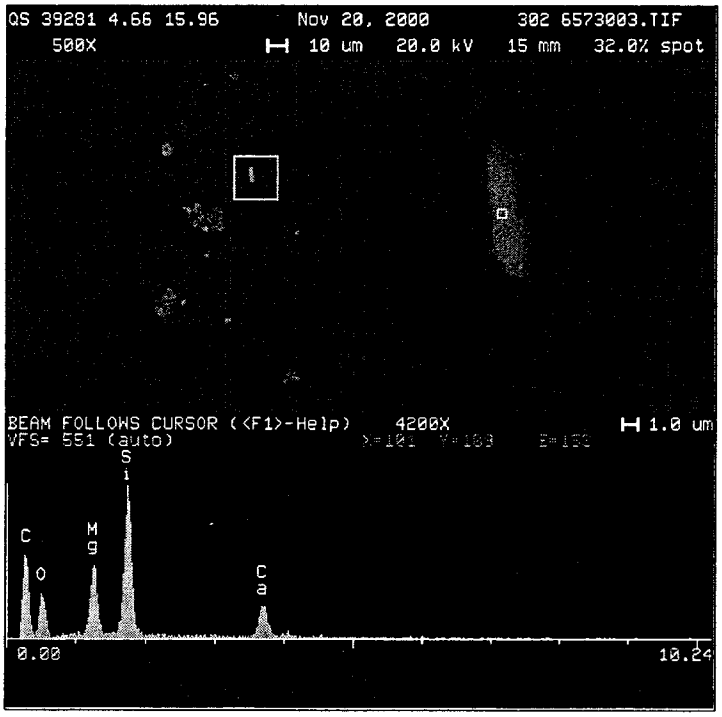

Figure 2. Backscattered electron image with EDS spectrum of tremolite particle.

RT Vanderbilt Co.
RJ Lee Group Project No. LSH006444
Sandpapered Paint (RJLG sample 3026573)

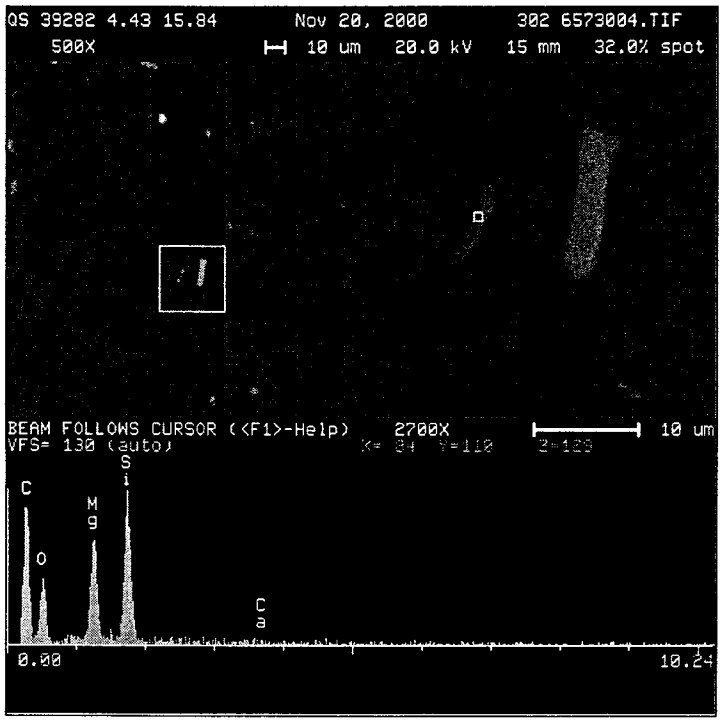

Figure 3. Backscattered electron image with EDS spectrum of fibrous talc particle.

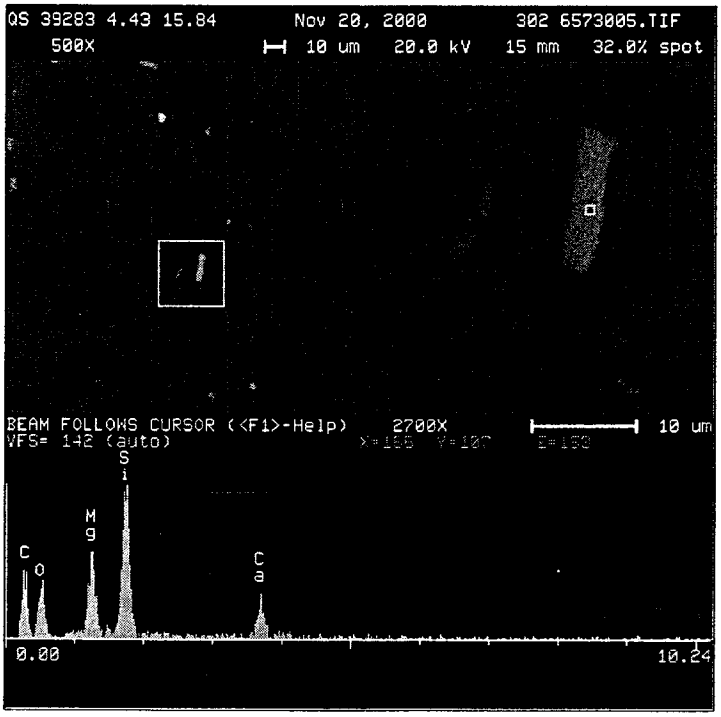

Figure 4. Backscattered electron image with EDS spectrum of tremolite particle.

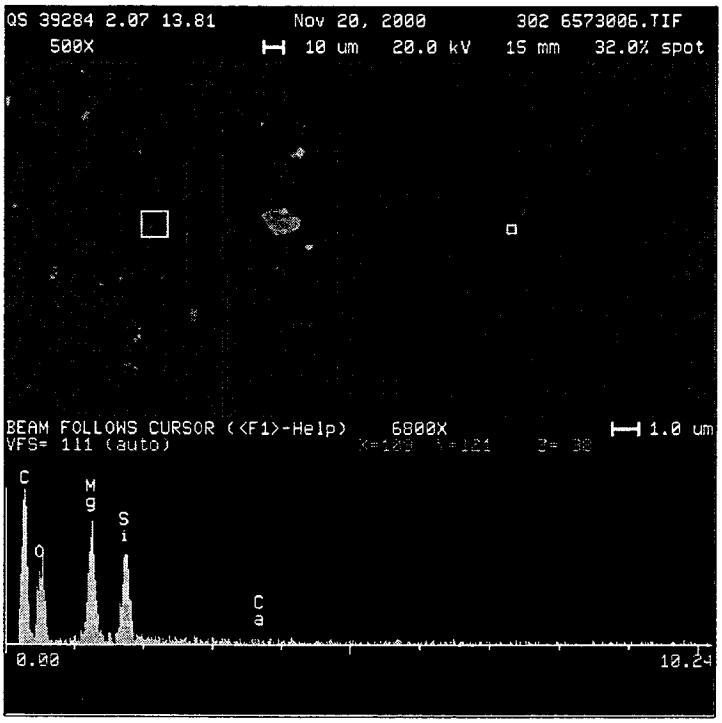

Figure 5. Backscattered electron image with EDS spectrum of fibrous talc particle.

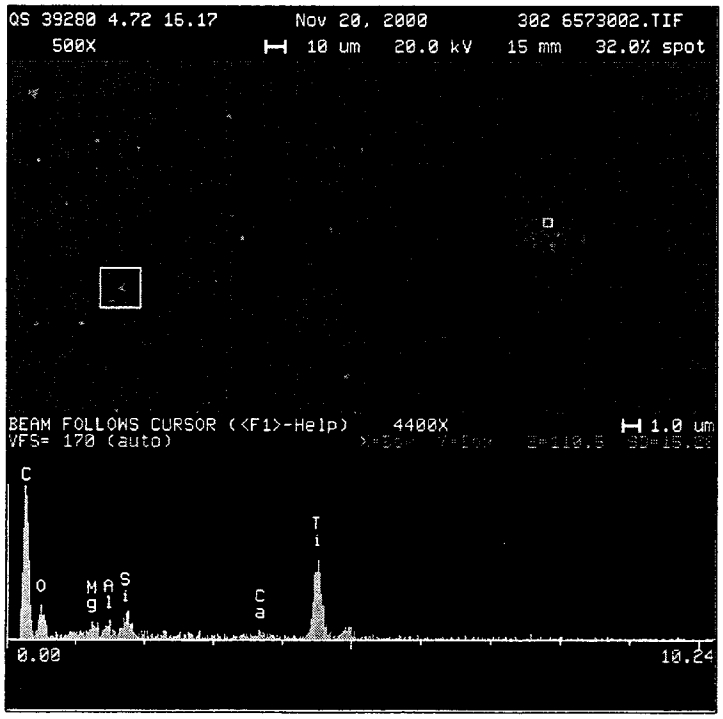

Figure 6. Backscattered electron image with EDS spectrum of paint particle.

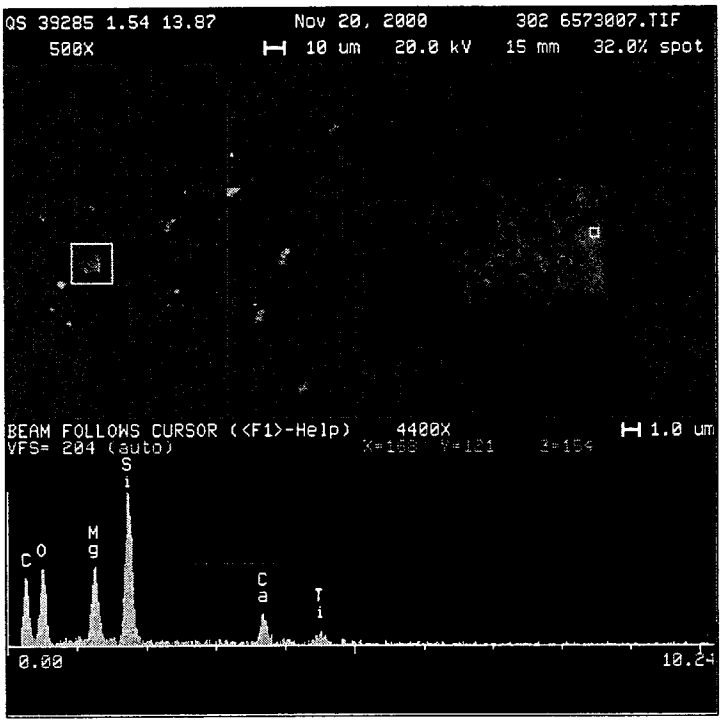

Figure 7. Backscattered electron image with EDS spectrum of tremolite particle incased in paint.

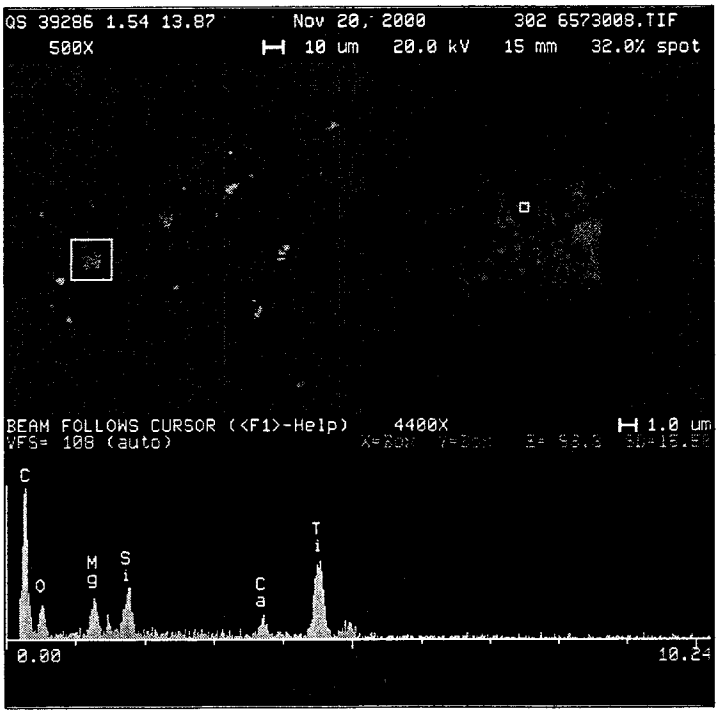

Figure 8. Backscattered electron image with EDS spectrum of paint particle.

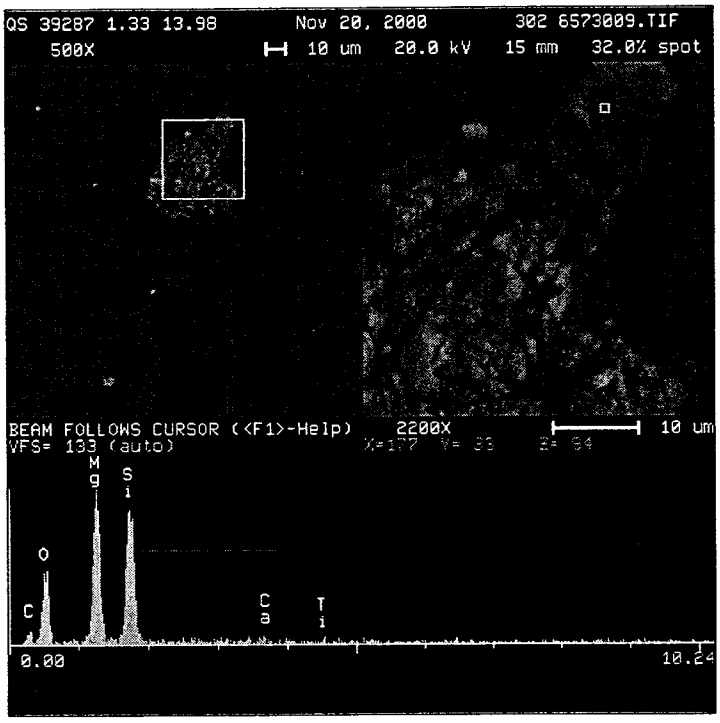

Figure 9. Backscattered electron image with EDS spectrum of talc particle encased in paint.

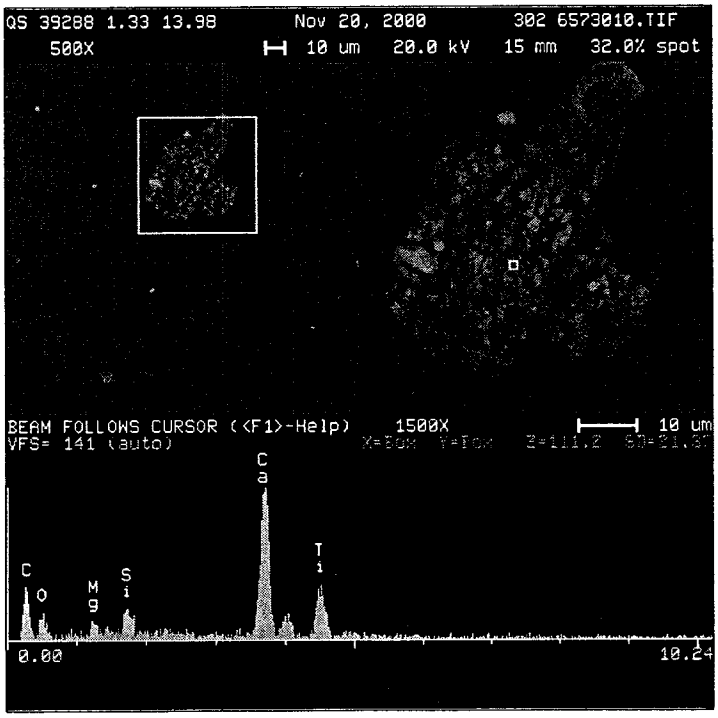

Figure 10. Backscattered electron image with EDS spectrum of paint particle.

RJ Lee*Group*, Inc.

350 Hochberg Road
Monroeville, PA 15146
Tel: (724) 325-1776
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The Materials Characterization Specialists

November 22, 2000

Mr. John W. Kelse
R. T. Vanderbilt Company, Inc.
30 Winfield Street
Norwalk, CT 06856-5150

RE: TEM Asbestos Analysis
RJ Lee Group Job No.: LSH006444-2

Dear Mr. Kelse:

Enclosed are the results from the transmission electron microscopy (TEM) asbestos analysis of the above referenced samples using the counting rules established by the NIOSH Method 7402, issue 2, 8/15/94. The sample and volume information were provided by R. T. Vanderbilt Company, Inc. personnel.

The analysis for asbestos fibers consisted of fiber morphology, visual selected area electron diffraction (SAED) and elemental chemical analysis by energy dispersive spectroscopy (EDS), supplemented by the measurement and interpretation of micrographs of several selected SAED patterns. The samples were analyzed at a magnification of 1,000 X. Particles meeting the definition of a fiber > 5 μm in length, > 0.25 μm in width, and having a length to width aspect ratio ≥ 3:1 were classified as chrysotile, amphibole asbestos, amphibole cleavage, or transitional fiber.

The attached table lists each sample identification number, filter area, volume, area analyzed, asbestos fiber counts (f_s), analytical sensitivity, concentration of asbestos (f/cc), total fibers counted (F_s), and asbestos fiber ratio (f_s/F_s). Copies of the count sheets are presented in Appendix A. Each sheet contains sample information pertaining to structure identification, dimensions, magnification, filter size, and type.

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If you have any questions, please feel free to call me.

Sincerely,

Drew R. Van Orden, PE
Senior Scientist

TEST REPORT

Asbestos Concentrations and Fiber Ratios

NIOSH 7402 Analysis

Project LSH006444-2

RJLG Sample Number	Client Sample Number	Filter Area (mm^2)	Volume (Liter)	Area Analyzed (mm^2)	Asbestos Fibers (f_s)	Analytical Sensitivity (f/cc)	Asbestos Concentration (f/cc)	Total Fibers (F_s)	Fiber Ratio (f_s/F_s)	Analysis Date
0114763HT	F-1	385	121.2	0.3301	0	0.0096	< 0.0096	1	0	11/13/00
0114764HT	F-2	385	120.2	0.3301	0	0.0097	< 0.0097	2	0	11/14/00
0114765HT	F-3	385	120.2	0.3301	0.5	0.0097	< 0.0097	1.5	0.33	11/14/00
0114766HT	F-4	385	Blank	0.3301	0	-	-	0	0	11/15/00

Volumes provided by R. T. Vanderbilt Company, Inc. were used to calculate analytical results and sensitivities. Analytical sensitivity is calculated based on one structure in the area analyzed.

Appendix A

TEM Count Sheets

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-2	RJLG QA Number	HQ18751
RJLG Sample #	0114763HT	Grid Openings	40
Client Sample #	F-1	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	1
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	121.1 Liters
Analyst	TWS	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
1	0			NSD						
2	0			NSD						
3	0			NSD						
4	0			NSD						
5	0			NSD						
6	0			NSD						
7	0			NSD						
8	0			NSD						
9	0			NSD						
10	0			NSD						
11	0			NSD						
12	0			NSD						
13	0			NSD						
14	0			NSD						
15	0			NSD						
16	0			NSD						
17	0			NSD						
18	0			NSD						
19	0			NSD						
20	0			NSD						
21	0			NSD						
22	0			NSD						
23	0			NSD						
24	0			NSD						
25	0			NSD						
26	0			NSD						
27	0			NSD						
28	0			NSD						
29	0			NSD						
30	0			NSD						
31	0			NSD						
32	0			NSD						
33	0			NSD						
34	0			NSD						
35	0			NSD						
36	0			NSD						
37	1	5.30	0.90	Amphibole		386		29795	Tremolite	Cleavage
38	0			NSD						
39	0			NSD						
40	0			NSD						

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-2	RJLG QA Number	HQ18751
RJLG Sample #	0114764HT	Grid Openings	40
Client Sample #	F-2	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	2
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	120.2 Liters
Analyst	RBG	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
1	0			NSD						
2	0			NSD						
3	0			NSD						
4	0			NSD						
5	0			NSD						
6	0			NSD						
7	0			NSD						
8	0			NSD						
9	0			NSD						
10	0			NSD						
11	0			NSD						
12	0			NSD						
13	0			NSD						
14	0			NSD						
15	0			NSD						
16	0			NSD						
17	0			NSD						
18	0			NSD						
19	0			NSD						
20	0			NSD						
21	0			NSD						
22	0			NSD						
23	0			NSD						
24	0			NSD						
25	1	15.60	2.00	Nonasbestos	M	287		None		
26	0			NSD						
27	0			NSD						
28	0			NSD						
29	0			NSD						
30	1	8.00	0.60	Nonasbestos		288		X		
31	0			NSD						
32	0			NSD						
33	0			NSD						
34	0			NSD						
35	0			NSD						
36	0			NSD						
37	0			NSD						
38	0			NSD						
39	0			NSD						
40	0			NSD						

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-2	RJLG QA Number	HQ18751
RJLG Sample #	0114765HT	Grid Openings	40
Client Sample #	F-3	Total Asbestos	0.5
Microscope	2000 FX	Total Non-Asbestos	1
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	120.2 Liters
Analyst	RBG	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
1	0			NSD						
2	0			NSD						
3	0			NSD						
4	0			NSD						
5	0			NSD						
6	0			NSD						
7	0			NSD						
8	0			NSD						
9	0			NSD						
10	0			NSD						
11	0			NSD						
12	0			NSD						
13	0			NSD						
14	0			NSD						
15	1	8.00	1.60	Amphibole		289		29812	Tremolite	Cleavage
16	0			NSD						
17	0			NSD						
18	0.5	10.00	1.00	Chrysotile	BM20			29814		
19	0			NSD						
20	0			NSD						
21	0			NSD						
22	0			NSD						
23	0			NSD						
24	0			NSD						
25	0			NSD						
26	0			NSD						
27	0			NSD						
28	0			NSD						
29	0			NSD						
30	0			NSD						
31	0			NSD						
32	0			NSD						
33	0			NSD						
34	0			NSD						
35	0			NSD						
36	0			NSD						
37	0			NSD						
38	0			NSD						
39	0			NSD						
40	0			NSD						

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-2	RJLG QA Number	HQ18751
RJLG Sample #	0114766HT	Grid Openings	40
Client Sample #	F-4	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	0
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	Blank
Analyst	TWS	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
1	0			NSD						
2	0			NSD						
3	0			NSD						
4	0			NSD						
5	0			NSD						
6	0			NSD						
7	0			NSD						
8	0			NSD						
9	0			NSD						
10	0			NSD						
11	0			NSD						
12	0			NSD						
13	0			NSD						
14	0			NSD						
15	0			NSD						
16	0			NSD						
17	0			NSD						
18	0			NSD						
19	0			NSD						
20	0			NSD						
21	0			NSD						
22	0			NSD						
23	0			NSD						
24	0			NSD						
25	0			NSD						
26	0			NSD						
27	0			NSD						
28	0			NSD						
29	0			NSD						
30	0			NSD						
31	0			NSD						
32	0			NSD						
33	0			NSD						
34	0			NSD						
35	0			NSD						
36	0			NSD						
37	0			NSD						
38	0			NSD						
39	0			NSD						
40	0			NSD						

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The Regulatory and Mineralogical Definitions of Asbestos and Their Impact on Amphibole Dust Analysis

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Although a familiar occupational health topic, the term *asbestos* generally is not well understood. Significant differences between mineralogical and regulatory definitions sustain the confusion. Definitional ambiguity is addressed and its effect upon the characterization of New York State tremolitic talc are investigated. Analysis of asbestiform and nonasbestiform airborne dust populations clearly demonstrates the nonspecificity of the regulatory definition and the 3:1 aspect ratio "fiber" counting scheme. Shifting to a higher aspect ratio would reduce false positives radically without a loss in sensitivity for true asbestos. Any change in aspect ratio, however, must be accompanied by a mineralogically correct definition of asbestos if proper mineral characterization is to be assured.

Introduction

Few environmental health hazards have been as widely publicized or viewed with as much dread as asbestos. Despite this attention, considerable confusion exists as to what the generic term *asbestos* actually means. American regulatory definitions are incomplete and, in some instances, at odds with the mineralogical view of this substance. The purpose of this paper is to review this definitional problem and demonstrate its effect on one controversial dust environment.

Definitions

Regulatory

The National Institute for Occupational Safety and Health (NIOSH) has established the definitions and analysis methods for asbestos used by almost all regulatory bodies in the United States. Under this scheme, asbestos is defined as any fiber of chrysotile, crocidolite, amosite, anthophyllite, tremolite or actinolite. A *fiber* is defined as a particle with a length to width ratio (aspect ratio) of at least 3:1 and a length of 5 μm or more as determined by the phase-contrast optical microscope (PCM) at a magnification of 450X to 500X.[1] While NIOSH acknowledges that this dimensional criteria and fiber counting method is not specific to asbestos,[2] regulatory definitions offer no further description of what is or is not asbestos.

Mineralogical

In the *Glossary of Geology*, asbestos is defined simply as

> A commercial term applied to a group of highly fibrous silicate minerals that readily separate into long, thin, strong fibers of sufficient flexibility to be woven, are heat resistant and chemically inert, and possess a high electrical insulation and therefore are suitable for uses where incombustible, nonconductive or chemically resistant material is required.[3]

While chemical and electrical inertness are properties shared by almost all silicates, asbestos is unique because of its long, thin, strong, flexible fibers. Accordingly, to a mineral scientist the term *asbestos* always includes some reference to the fibrous crystal growth pattern often described as the "asbestiform habit." Mineralogically, asbestos is a matter of how a mineral grows, not simply a matter of one mineral versus another or an arbitrary dimensional concept.

Several minerals, including those designated in United States' regulations, do grow in nature in an asbestiform habit. These would include the most commonly exploited forms of asbestos: chrysotile, crocidolite, and amosite. The regulated asbestiform minerals, however, also occur in nature in a nonasbestiform habit. In all cases, the nonasbestiform habit is by far the more common. Table I lists the asbestiform and nonasbestiform habits of the six regulated minerals and their separate Chemical Abstract Service numbers. The list conforms to the nomenclature set forth by the United States Department of the Interior.[4]

It should be noted that the chemical composition is the same for each mineral in either growth habit. In all cases except chrysotile, the internal crystal structure is identical as well. Also, the first three minerals have been assigned separate names to distinguish the different growth patterns, while the last three—anthophyllite, tremolite, and actinolite—have not. For these three the nonasbestiform analogs are common rock-forming minerals found throughout the earth's crust and, therefore, routinely encountered in many industries. Figure 1 graphically depicts the basic difference in the two mineral growth patterns while Figure 2 contrasts the two macroscopically and microscopically.

While nonasbestiform particles clearly differ from asbestiform particles, many would be counted as asbestos under the current regulatory 3:1 dimensional criterion for a fiber when an ore is crushed, milled or otherwise reduced. Thus, while all asbestos is fibrous, not all fibers are asbestos. It is also important to note that asbestiform fibers cannot be created from nonasbestiform materials by crushing, milling, or grinding. Mineralogically, a particle with an aspect ratio of 3:1 would not be considered a fiber. Because the term *fiber* is interpreted in different ways, its use in this paper will be restricted

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TABLE I
Asbestiform and Nonasbestiform Varieties of Selected Silicate Minerals and Their Chemical Abstract Service Numbers (CAS)

Asbestiform Variety (CAS #)	Chemical Composition	Nonasbestiform Variety (CAS #)
Serpentine Group:		
Chrysotile (12001-29-5)	$Mg_3(Si_2O_5)(OH)_4$	antigorite, lizardite (12135-86-3)
Amphibole Group:		
Crocidolite (12001-28-4)	$Na_2Fe_3Fe_2(Si_8O_{22})(OH,F)_2$	riebeckite (17787-87-0)
Grunerite asbestos (amosite) (12172-73-5*)[A]	$(Mg,Fe)_7(Si_8O_{22})(OH,F)_2$	cummingtonite-grunerite (14567-61-4)
Anthophyllite asbestos (77536-67-5*)	$(Mg,Fe)_7(Si_8O_{22})(OH,F)_2$	anthophyllite (17068-78-9)
Tremolite asbestos (77536-68-6*)	$Ca_2Mg_5(Si_8O_{22})(OH,F_2)$	tremolite (14567-73-8)
Actinolite asbestos (77536-66-4*)	$Ca_2(Mg,Fe)_5(Si_8O_{22})(OH,F)_2$	actinolite (13768-00-8)

[A]The presence of an asterisk following a CAS Registry Number indicates that the registration is for a substance which CAS does not treat in its regular CA index processing as a unique chemical entity. Typically, this occurs when the material is one of variable composition: a biological organism, a botanical entity, an oil or extract of plant or animal origin, or a material that includes some description of physical specificity, such as morphology.

in the interest of clarity to specific definitions only. To reflect the mineralogical characteristics of asbestos in a definition, a group of mineral scientists agreed to the following.[5]

A. Asbestos—A collective mineralogical term that describes certain silicates belonging to the serpentine and amphibole mineral groups, which have crystallized in the asbestiform habit causing them to be easily separated into long, thin, flexible, strong fibers when crushed or processed. Included in the definition are chrysotile; crocidolite, asbestiform grunerite (amosite); anthophyllite asbestos; tremolite asbestos; and actinolite asbestos.

B. Asbestos Fibers—Asbestiform mineral fiber populations generally have the following characteristics when viewed by light microscopy:
   1. Many particles with aspect ratios ranging from 20:1 to 100:1 or higher ($> 5\ \mu m$ length)
   2. Very thin fibrils generally less than $0.5\ \mu m$ in width, and
   3. In addition to the mandatory fibrillar crystal growth, two or more of the following attributes:
      (a) Parallel fibers occurring in bundles;
      (b) Fibers displaying splayed ends;
      (c) Matted masses of individual fibers; and
      (d) Fibers showing curvature[5]

Many of those who contributed to this definition and support the listed criteria have published extensively on the problems associated with the NIOSH definitions and the membrane filter method.[4,6-17] This definition has been incorporated in a proposed American Society for Testing and Materials (ASTM) method submitted to committee D-22.05 (January 14, 1988). The criteria have long been endorsed by the U.S. Department of the Interior.[4,11,13]

While all mineral scientists may not agree with every entry in this definition, it does present a more mineralogically accurate description of asbestos and asbestos fibers than does the regulatory definition. This is especially true when it is applied to a dust population rather than on a particle by particle basis. The definition, therefore, will be used in the remainder of this paper as the "mineralogical" definition of asbestos. It might be noted that the width criterion ($0.5\ \mu m$) represents a dimension below which all individual "fibrils" and clumps or masses of fibrils would be encountered in processed asbestos. Unprocessed clumps or masses may exceed this width, but such particles would not be representative of common airborne asbestos fibers.

The Study Environment

One of the most controversial workplace exposures associated with this definitional issue involves the mining and milling of New York State tremolitic talc. Accordingly, a study was undertaken to contrast dust data obtained in this environment with both the regulatory and mineralogical definitions discussed above.

New York State tremolitic talc is an industrial grade talc used extensively in the ceramics, tile, and paint industries. Since 1974 the R.T. Vanderbilt Company, Inc., has owned and operated the only New York State tremolitic talc mine.

Talc mined from this operation varies somewhat in mineral content but an assay of the ore generally reflects 40%–60% tremolite, 1%–10% anthophyllite, 20%–40% talc, 20%–30% serpentine (antigorite-lizardite), and 0%–2% quartz.[18]

The R.T. Vanderbilt Company states that all of the tremolite and anthophyllite in its talc products appear only in the nonasbestiform habit.[19,20] In 1980, however, NIOSH published a technical report entitled *Occupational Exposure to Talc Containing Asbestos*[21] specifically addressing this mineral dust exposure. In the report, NIOSH applied its regulatory asbestos definition to bulk and airborne dust samples collected at this mine and reported over 70% asbestos for airborne fibers satisfying the 3:1 or greater aspect ratio and greater than 5-μm length limit (NIOSH PCM method). Particles were identified as tremolite and anthophyllite by standard X-ray diffraction technique.

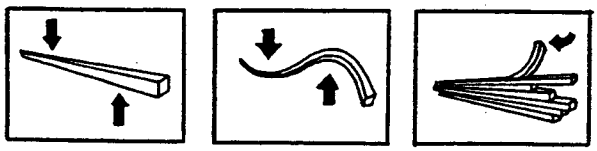
Method of Study

Samples for particulate analysis were collected on open-faced, 37-mm diameter Millipore type AA filters (0.8-μm pore size, Millipore Corp., Bedford, Mass.). Precalibrated Mine Safety Appliances' Model G pumps were used to draw air through these filters at a rate of 1.7 L/min. Although fiber sampling technique has changed since, this technique was used in order to compare results with data previously collected. Filters were changed throughout a full work shift as needed to prevent overloading. In all, 22 air samples were obtained representing nine work activities in the R.T. Vanderbilt Co., Gouverneur, New York, mine and mill. Work activities sampled included milling (Hardinge and Wheeler mills), drying, packing, bag stacking, crushing, mine drilling, scraping, and tramming.

Analyses were performed by The R.J. Lee Group, Inc., of Monroeville, Pennsylvania (Project No. 86-12318). Analytical techniques employed included phase contrast microscopy (PCM), polarized light microscopy (PLM), scanning electron microscopy (SEM), computer-controlled scanning electron microscopy (CCSEM), and transmission electron microscopy (TEM). In accordance with NIOSH method 7400, all samples received PCM particle counts at 400X magnification in Walton-Beckett graticule measuring at least 5-μm long with a 3:1 or greater aspect ratio. Beyond these specified parameters, exact particle widths and lengths were not measured. For each sample, 100 fields or 100 particles, whichever came first, were counted (with a minimum of 20 fields). In all, 2295 particles were counted and sized by PCM.

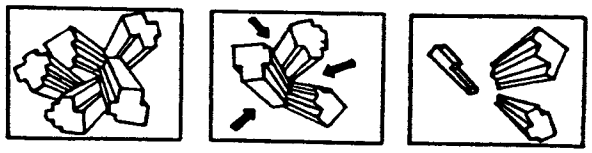
A separate wedge was cut from each filter for PLM analysis. Particles were tapped, then gently scraped from the wedge to a glass slide. Any remaining particles were captured by rolling a needle moistened with 1.592 refractive index (RI) liquid over the surface of the filter wedge (RI selected for low-iron talc). Additional 1.592 RI liquid was added to the slide and used to wash particles from the needle onto the slide. It should be noted that this transfer technique could bias the PCM analysis if very fine particles were lost in the transfer. Additional analysis of particles not removed from the filter (another filter section) suggests such bias is unlikely for tremolite (see SEM particle width discussion below). PLM counts were made in a 1.592 RI oil to differentiate talc from all amphiboles on all 22 air samples. Following this basic cut, tremolite was differentiated from anthophyllite by angle of extinction (tremolite has an inclined extinction of 14° to 17°, while anthophyllite exhibits parallel extinction). Since all asbestos exhibits parallel extinction, mineral habit (asbestiform or nonasbestiform) then was decided on the basis of criteria noted in the mineralogical definition. Depending on particle concentration for each of the 22 samples, 100 to 200 points were counted and characterized at 100X magnification, yielding a minimum of 2200 particles subjected to PLM analysis. If positive particle identification could not be made at 100X total magnification, higher magnifications (up to 400X) were applied on a particle by particle basis. As in the PCM analysis, only particles with an aspect ratio of 3:1 or greater and a length of 5 μm or more were so characterized. Although exact length and width measurements were not obtained, particles were sized by basic aspect ratio categories (*i.e.*, those 3:1 or greater, 10:1 or greater, *etc.*). One additional step was taken in the PLM analysis in which particles presumed to be anthophyllite (> 1.592 RI) were tested for "transitional" phases (meaning talc intertwined with or evolving from anthophyllite and/or biopyriboles). This was accomplished by finding particles which most closely approximated the same size and morphological characteristics of these suspect particles on another portion

ASBESTIFORM



In the asbestiform habit, mineral crystals grow in a single dimension, in a straight line until they form long, thread-like fibers with aspect ratios of 20:1 to 1000:1 and higher. When pressure is applied, the fibers do not shatter but simply bend much like a wire. Fibrils of a smaller diameter are produced as bundles of fibers are pulled apart. This bundling effect is referred to as polyfilamentous.

NONASBESTIFORM



In the nonasbestiform variety, crystal growth is random, forming multidimensional prismatic patterns. When pressure is applied, the crystal fractures easily, fragmenting into prismatic particles. Some of the particles or cleavage fragments are acicular or needle-shaped as a result of the tendency of amphibole minerals to cleave along two dimensions but not along the third. Stair-step cleavage along the edges of some particles is common, and oblique extinction is exhibited under the microscope. Cleavage fragments never show curvature.

Figure 1—Asbestiform and nonasbestiform graphics

RAW ORE

EXAMPLES

Amphiboles with Separate Names:

amosite

cummingtonite-grunerite

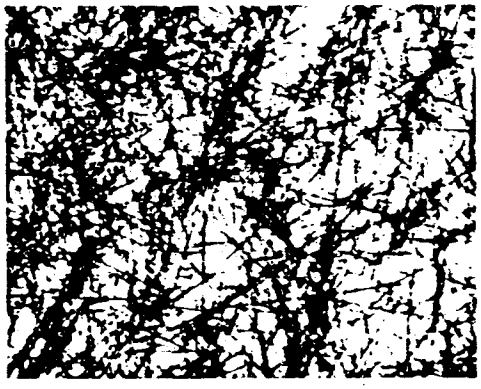
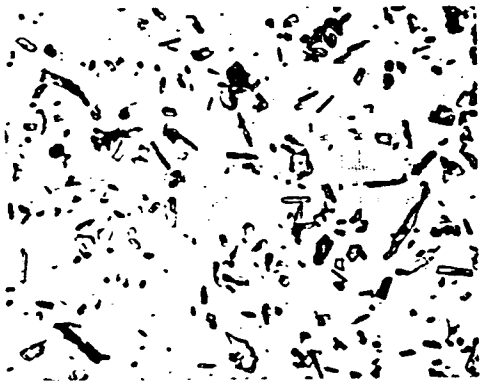
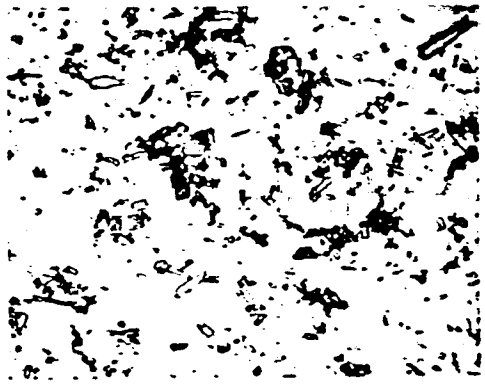
Amphiboles with the Same Name:

tremolite

tremolite

MICROSCOPIC

265X Magnification, 2.75 μm/Division

EXAMPLES	ASBESTIFORM	NONASBESTIFORM
Amphiboles with Separate Names:	 amosite	 cummingtonite-grunerite
Amphiboles with the Same Name:	tremolite	 tremolite

of the filter and testing them at 1.608 RI (the low gamma index for anthophyllite). Because of problems inherent in this technique, testing the same particle with different RI liquids was not possible. Particles with an index of refraction between 1.592 and 1.608 were classed as "transitional." In all, 6 samples underwent this additional analysis.

To test further the differences and similarities between asbestiform dust populations and the tremolitic talc dust environment, electron microscopy was employed on 5 samples most representative of common mine and mill exposures (*e.g.*, product packaging). SEM with energy dispersive X-ray (EDX) first required the mounting of another 1/8 filter wedge from each sample on a carbon-coated stub. Fifty fields at 2000X magnification then were analyzed for count, size, and identity of all particles in every field with an aspect ratio greater than 3:1 and a length greater than 5 μm. For the five filters, a total of 183 particles were characterized in this way. Particles below and above a width of 0.25 μm were noted as well. This width was selected primarily because it is used in references against which the findings of this study shall be compared.[6,7,22,23] These references generally refer to this width as the approximate lower resolution limit of the light microscope.[24] While other references report lower width sensitivity,[25,26] it generally is agreed this lower limit varies with the quality of the microscope, use of dispersion staining and background contrast, magnification, and the microscopist involved. CCSEM with EDX was used on the same carbon-coated filter wedges to scan a total of 2500 particles (500 per sample) at magnifications of 35X, 100X, and 500X. Particles were sized by the preselected parameters, and the chemical composition of all particles was noted. Particle distribution was expressed in volume percent and all tremolite particles were counted. TEM with selected area electron diffraction (SAED) also was employed on new carbon-coated filter wedges from the same five filters. Chemical composition by EDX analysis and SAED patterns of individual fibers which measured 10 μm or greater on four grid squares per wedge were obtained after the filter matrix was dissolved from the carbon film. While considerable data were thus generated from this multiple analytical approach, only data summaries which directly address the definitional comparison are included in this paper.

It should be noted that the EDX chemistries obtained through the CCSEM analysis and the SAED patterns obtained through TEM analysis were not adequate to distinguish talc and anthophyllite. While an in-depth discussion of this problem is beyond the scope of this paper, in summary it should be said that talc may present the same X-ray spectrum as anthophyllite because talc displays a similar 2:1 Si/Mg ratio and overlapping range. Regarding SAED patterns, talc in the fibrous form often reflects the same 5.3 Å spacing as anthophyllite. Talc/anthophyllite in an intermediate or transitional phase poses further identification problems when electron diffraction analysis is restricted to one point per particle. This is more fully described in other papers.[27,28]

Study Results and Definitional Comparison

Table II contrasts bulk tremolite asbestos particles described in the literature[12] to tremolite particles reflected on five New

TABLE II
Ratio Comparison of Bulk Tremolite Asbestos[A] to N.Y. State Tremolite in Five Air Samples[B] by Optical and Electron Microscopy

Samples	Ratio of Tremolite Particles				
	3:1 aspect ratio (a.r.) or Greater to Total Tremolite (> 5 μm length) SEM[C]	10:1 a.r. or Greater to Total Tremolite (> 5 μm L) SEM	20:1 a.r. or Greater to Total Tremolite (> 5 μm L) SEM	10:1 a.r. or Greater to 3:1 a.r. or Greater Opt[D]	SEM
Tremolite asbestos[E]	1 in 1.6	1 in 2.6	1 in 4.6	1 in 1.6	1 in 1.6
Tremolite asbestos[F]	1 in 1.8	1 in 2.3	1 in 2.5	1 in 1.6	1 in 1.2
# total tremolite particles per sample (all sizes): 200	(approx. 55%)	(approx. 41%)	(approx. 31%)	1 in 1.5 (66%)	
Tremolite in 5 N.Y. air samples[B]	1 in 6.2	1 in 949 or greater	0 in 949	Opt. 1 in 141 or greater	CCSEM 1 in 152 or greater
# total tremolite particles (all sizes): 949	(16%) CCSEM	(0.1%) CCSEM	(0%) CCSEM	1 in 146 or greater (0.6%)	

[A]Data from U.S. Dept. of Interior, Bureau of Mines Report of Investigation 8367, page 13, Table 2 (1979).[12]

[B]Present study: CCSEM analysis of 5 air samples at 35X, 100X, and 500X magnifications. (2500 total particle count [all sizes]). Optical (PCM and PLM) analysis of the same 5 samples up to 400X magnifications (534 total particles with a 3:1 a.r. or greater > 5 μm length).

[C]Particles counted using SEM with magnification up to 50 000X.

[D]Particles counted using optical-light microscopy at 1250X magnification (200 tremolite particles counted per filter).

[E]Obtained from California (no other description of literature). Wiley milled.

[F]Obtained from museum sample from Rajasthan, India. Wiley milled.

TABLE III
Average of 22 Mine and Mill Air Samples (2295 Particles) by Composition, Aspect Ratio 3:1 or Greater (> 5 μm length), and Mineral Habit by Light Microscopy[A]

	% of Total			Particles per CC (TWA)			Total Particles per CC	% Asbestiform by
Aspect Ratio:	3:1-10:1	> 10:1-20:1	> 20:1	3:1-10:1	> 10:1-20:1	> 20:1	(8-hr TWA)	Mineralogical Def.
Tremolite	35.8	.33	0	.45	.009	0	0.459	0
Transitional[B]	0.0	.76	0	0.00	.015	0	0.015	0
Talc	58.2	4.60	0	.67	.058	0	0.728	0
All particles	93.0	7.00	0	1.12	0.082	0	1.210	0

[A]Mineral type and % by aspect ratio were obtained by PLM analysis at 100X to 400X magnification. Total particles per cc were obtained by PCM at 400X magnification.

[B]% Talc/anthophyllite transitional particles were extrapolated from 6 of 22 air samples based on a refractive index between 1.592 and 1.608 for the gamma index. No pure anthophyllite particles were noted in the fields analyzed.

York state tremolitic talc air samples by both optical and electron microscopy. In this comparison, the ratio of tremolite particles which satisfy the regulatory definition of a fiber (3:1 or greater aspect ratio, > 5 μm length) and those that exceed a 10:1 and 20:1 aspect ratio (> 5 μm length) are addressed.

Of the 2500 total particles scanned by CCSEM on 5 air samples, 38% or 949 were tremolite. Of these tremolite particles, 16% or 152 satisfied the regulatory size criteria for a fiber. This represents a ratio of 1 tremolite regulatory fiber in every 6.2 tremolite particles. In contrast, tremolite asbestos reflected an average of 1 regulatory size fiber in every 1.7 particles (55%). Most striking, however, is the difference reflected at 10:1 and 20:1 aspect ratios. For the New York state tremolite, only 1 tremolite particle in 949 (total counted) exceeded a 10:1 aspect ratio (0.1%). For tremolite asbestos this ratio was approximately 1 in every 2.5 particles or 40%. At a 20:1 aspect ratio or greater, no New York tremolite particles were counted, while 1 in every 3 (approximately) were found for tremolite asbestos. Significant variation in these ratios was not noted under optical microscopy for the same samples at the magnifications applied.

While a bulk to airborne particle comparison is not ideal, the dimensional differences likely would be even greater if two airborne particle distributions were compared, since wider width, lower aspect ratio particles are more common in bulk particle distributions. Published particle distributions for airborne asbestos dust populations support this contention and support the basic dimensional similarity of tremolite asbestos to other asbestiform minerals (see the extended discussion on airborne particle aspect ratio distributions below). Accordingly, on a tremolite to tremolite basis, an entirely different particle-size distribution would be expected in the New York state tremolitic talc samples if this tremolite were asbestiform.

Table III reflects the average of all 22 air samples by percent mineral composition, aspect ratio (3:1 or greater), and crystal growth habit (asbestiform or nonasbestiform). Results in this table reflect the combined application of the PCM and PLM methods outlined above.

In the fields analyzed by PLM, no particles exceeded a 20:1 aspect ratio or showed splayed ends, curvature, or parallel fibers occurring in bundles. Using the mineralogical definition, therefore, no asbestos was found; however, 0.459 particles/cc would be noted if the regulatory definition were used (talc and transitional particles excluded). A total of 1.21 particles/cc would be reported if talc and transitional particles were counted. Proper characterization of talc, anthophyllite and transitional particles is extremely difficult in this ore body except by PLM. While PLM air sample data reflect no asbestiform fibers, both talc and transitional particles can appear in a fibrous, asbestiform and/or nonasbestiform habit in this ore body.[27] If misclassified as anthophyllite, these asbestiform fibers would be characterized as asbestos under both the regulatory and mineralogical definitions. TEM/SAED analysis with multiple electron diffraction patterns (each indexed) confirmed the presence of both nonasbestiform and asbestiform transitional and fibrous talc particles in a random scan of fields not included in the PLM analysis. No effort to quantify these fibers was made. Because of the rarity of these fibers and their marginal significance to the definitional distinctions being addressed here, further detail in this area is beyond the scope and intent of this paper.

Table IV reflects a comparison of fiber counts obtained in this study with data previously obtained in the same mine and mill (same or similar work activities). These data confirm a marked difference in what is reported as asbestos, depending upon the definition used. Note that the average of all regulatory fibers counted by PCM (Column 2) shows far less variance between investigators than the percent of particles considered asbestiform (Column 5). Mineralogical distinctions made reflect consideration of the characteristics described in the mineralogical definition. Although none of the particles in the study dust population exceeded a 20:1 aspect ratio by light microscopy, this factor alone did not dictate habit characterization for the 22 samples analyzed. Although the lack of 20:1 aspect ratio particles in a dust population certainly suggests a nonasbestiform dust environment, aspect ratios alone are not pivotal in a mineralogical sound definition of asbestos.

To test definitional specificity further, a comparison of basic dimensional characteristics common to asbestiform dust populations, nonasbestiform (cleavage fragment) amphi-

TABLE IV
Historical Air Samples[A] by Definitional Approach

Source and Year	Average of All Particles/CC Mill and Mine	Range Particles/CC Mill and Mine[(n)B]	Definitional Approach	% Particles/CC Classed as Asbestos	Particles/CC Considered Asbestos
R. Lee (1988)	1.21	0.14-3.56[22]	mineralogical	0.00	0.000
MSHA (1984-85)[C]	2.39	0.14-18.40[38]	mineralogical	0.40	0.009[D]
Insurance (1984)[E]	1.8	1.38-2.15[5]	not classed	—	—
NIOSH (1975)[F]	4.6	1.5-8.4[221]	regulatory	72.00	3.312
Dunn (1982)[G]	0.65	0.03-1.38[8]	mineralogical but classification completed on bulk samples only	—	—

[A]All particles 3:1 or greater in aspect ratio, > 5 μm in length and resolvable under the light microscope.

[B](n) = number of air samples.

[C]Mine Safety and Health Administration Survey Reports dated: 7/17/85, 7/30/85, 5/22/85, 6/12/84, 1/9/84.

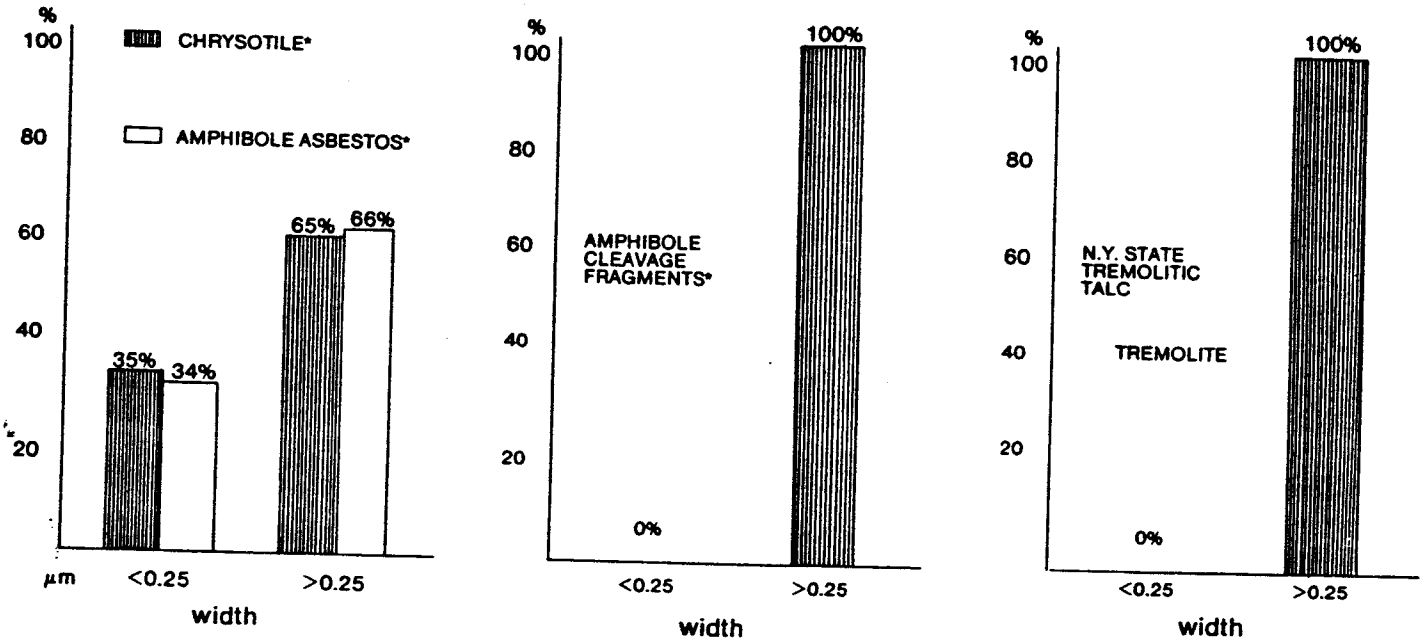
[D]MSHA performs analysis for fiber type only on filters with elevated total fiber counts. Of the 38 filters, 22 were so analyzed. Of these, 2 filters were reported as containing 2% asbestiform fibers. All other filters were found or assumed to contain 0%.

[E]Hartford Insurance Company Report dated November 1984 to R.T. Vanderbilt Company, Inc.

[F]NIOSH Technical Report, *Occupational and Exposure to Talc Containing Asbestos*, Table 7 (1980).[21]

[G]Dunn Geoscience Corp. report to R.T. Vanderbilt Company (1985).

bole dust populations, and the study dust population was undertaken. Figure 3 compares airborne asbestiform and nonasbestiform particles which fall above and below a width of 0.25 μm, described in the literature,[22] with study dust population particle widths obtained by SEM. With regard to the tremolite found in the talc air samples (the only amphibole noted), all tremolite particles (88 out of 183 total particles) were wider than 0.25 μm. Particle widths noted in



*From: J.G. Snyder, R.L. Virta, and J.M. Segret: "Evaluation of the Phase Contrast Microscopy Method for the Detection of Fibrous and Other Elongation Mineral Particulates by Comparison with a STEM Technique," *Am. Ind. Hyg. Assoc. J. 48(5)*:471-477 (1987) Table IV. Average of 17 air samples.

From: Average of 5 air samples analyzed by SEM (represents 88 particles out of 183 total particles).

Figure 3—Average airborne particle width comparison by electron microscopy (all particles 3:1 or greater aspect ratio, 5 μm or more length).

TABLE V
Aspect Ratio Comparison

Airborne Asbestos Particles[A] (Mining and Bagging) > 0.25 μm Width, > 5 μm Length					Airborne Cleavage Fragments[B] (Approx. 4500 Total Particles) > 0.25 μm Width, > 5 μm Length				
	% of Particles Seen at:					% of Particles Seen at:			
Aspect Ratio:	3:1	10:1	15:1	> 20:1	Aspect Ratio:	3:1	10:1	15:1	> 20:1
Crocidolite	100	100	91.5	64.5	cummingtonite	100	24	10	6
Amosite	100	100	89.5	58.0	cummingtonite	100	32	7	3
Chrysotile	100	100	86.0	37.0	actinolite	100	15	4	3
Average:	100	100	89	53	grunerite/actinolite	100	8	0	0
					tremolitic talc[C]	100	7	ND[D]	0
					Average:	100	17	5	2.4

[A]Taken from G.W. Gibbs and C.Y. Hwung, *Dimensions of Airborne Asbestos Fibers*, IARC Scientific Pub. #30 Lyon, France, pp. 79-86.[23]

[B]Taken from A.G. Wylie, R.L. Virta, and E. Russek, "Characterizing and Discriminating Airborne Fibers: Implications for the NIOSH Method," *American Industrial Hygiene Association Journal*, Vol. 46, pp. 197-201.[7]

[C]Data taken from the R.J. Lee Group Dust Analysis Project prepared for the R.T. Vanderbilt Co., Inc., 1988. Reflects PCM/PLM analysis of 22 fillers; % represents 2295 total particles.

[D]ND = not determined.

asbestiform dust populations by STEM differ markedly, with an average of 35% (ranging from 9% to 81%) reported to fall below a 0.25-μm width.[22] The similarity between amphibole cleavage fragment particle width and tremolite widths noted in the study dust population, therefore, suggests a nonasbestiform habit. It also might be noted that since all tremolite particles exceeded a 0.25-μm width, they should all be resolvable at the lower magnifications used for both PCM and PLM analysis. Further, it is unlikely that particles of this width would be lost in the transfer of particles from the filter to the glass slide in preparation for the PLM analysis.

In terms of aspect ratio, major differences between nonasbestiform amphibole cleavage fragments and asbestiform particles also exist. Table V makes such a comparison for airborne particles which meet or exceed a 3:1 aspect ratio and a greater than 5-μm length. Variances shown in this table typically are found in the literature.[6,7,23] Figure 4 graphically depicts these data and further clarifies the difference. In terms of the study dust population, particle aspect ratio distribution is included in Table V under the cleavage fragment column where it best fits. Interestingly, total particulate aspect ratios noted in this study (based on 2295 particles) would represent the low end of the cleavage fragment line in Figure 4. Unfortunately, an airborne dust size characterization for asbestiform tremolite could not be found for inclusion in this comparison. Although asbestiform tremolite is rare and is not exploited for commercial use, localized occurrences do exist in the United States (*i.e.*, California, Montana). At least one industrial hygiene study exists of a mining operation containing asbestiform tremolite, but detailed airborne size characterization is not available.[29] An aspect ratio distribution, however, was obtained on bulk asbestiform tremolite from this mine.[30] For particles longer than 5 μm, 88% fell above 10:1, 70% above 15:1, and 52% above 20:1. These ratios correlate most closely to the average airborne asbestos ratios reflected in Table V and Figure 4 of 100%, 89%, and 53%, respectively.

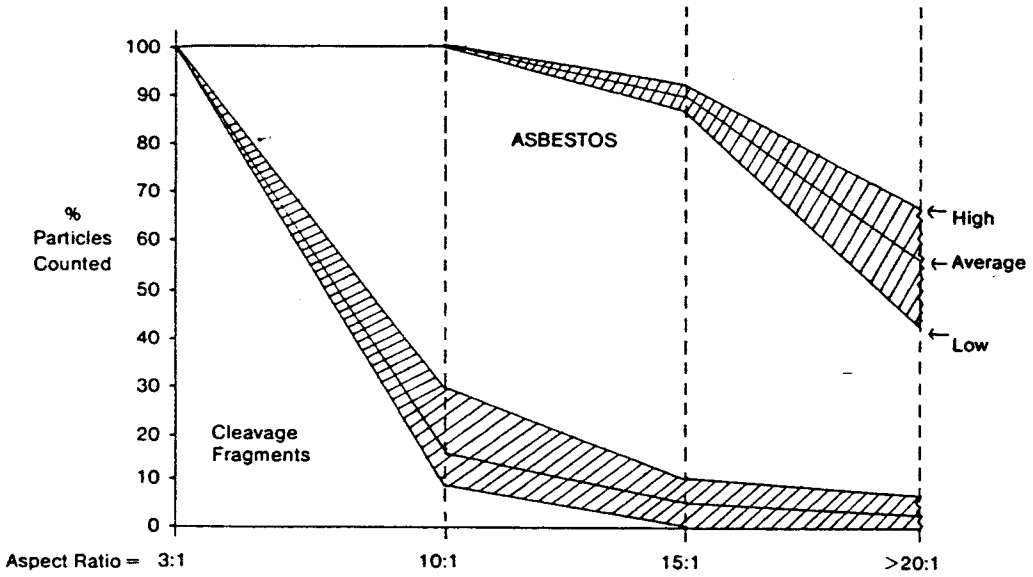
In summary, when the study dust population is contrasted with the mineralogical definition—as well as the dimensional characteristics of asbestiform and nonasbestiform particles reflected in the literature—the nonasbestiform nature of New York state tremolitic talc is quite apparent. The authors believe this reaffirms the nonspecificity of the NIOSH PCM method and the regulatory definitions it underpins when applied to mineral dust environments containing common nonasbestiform cleavage fragments.

Corrective Measures

Given the differences between asbestiform and nonasbestiform particulates, the least dramatic change necessary to improve specificity would involve an upward adjustment in the aspect ratio. As seen in Figure 4, airborne asbestiform particles exceed a 10:1 aspect ratio with very few less than 15:1. Cleavage fragments, in contrast, rarely exceed a 10:1 aspect ratio with fewer still exceeding 15:1. Any aspect ratio adjustment, however, should be applied as a screening tool only because there is some aspect ratio overlap between asbestiform and nonasbestiform particles. It, therefore, is considered essential that a mineralogically correct definition of asbestos and criteria specific to asbestos should be reflected in regulations.

Discussion

Although it is not the intent of this paper to address health issues, the subject cannot be ignored in any discussion regarding the definition of asbestos. It can be argued, for example, that regulatory definitions are designed to address human health concerns and not the realities of physical science. This argument suffers, however, when it is under-



NOTE: The majority of cleavage fragments do not fall in this range (most reflect lengths of $< 5\ \mu m$). The 100%, therefore, represents the starting point for 3:1 aspect ratio particle counting and not the total % of airborne cleavage fragments.

Figure 4—Airborne asbestos versus cleavage fragment aspect ratio comparison (particules with an aspect ratio of 3:1 or greater, $> 5\ \mu m$ length, $> 0.25\ \mu m$ width). From Table V.

stood that health effects attributable to asbestos are not reasonably demonstrated for nonasbestiform exposures.[31-38] Moreover, it can be argued that any environmental exposure ought to be studied and regulated for what it is. To do otherwise presents needless bias.

It also has been argued that any change in the regulatory definition of asbestos would confuse the extensive data base developed for commercially used asbestos. Nonasbestiform amphiboles, however, cannot and are not used for applications typically reserved for asbestos (*e.g.*, insulation, structural binding, fire proofing, brake linings, *etc.*). Accordingly, this asbestos data base would not be affected significantly if a mineralogically correct definition of asbestos were adopted. The definitional ambiguity discussed here relates to dust populations which do contain nonasbestiform mineral cleavage fragments. Such environments commonly involve hard rock and aggregate mining operations and industries who use their mineral products (*e.g.*, ceramics, construction, paint, *etc.*). Whatever asbestos data exist for these environments may be misleading and, therefore, ought to be corrected.

Conclusion

Major differences in crystal growth patterns, lengths, and widths exist between asbestiform particles and common, hard rock-forming mineral cleavage fragments. Current regulatory asbestos definitions and fiber quantification methods do not address these distinctions adequately. Thus, nonasbestiform dust populations can and have been mistaken as asbestiform. Confusion is likely to persist until a regulatory definition and analytical approach specific to asbestos is adopted.

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The Materials Characterization Specialists

November 22, 2000

Mr. John W. Kelse
R. T. Vanderbilt Company, Inc.
30 Winfield Street
Norwalk, CT 06856-5150

RE: TEM Asbestos Analysis
RJ Lee Group Job No.: LSH006444-3

Dear Mr. Kelse:

Enclosed are the results from the transmission electron microscopy (TEM) asbestos analysis of the above referenced samples using the counting rules established by the NIOSH Method 7402, issue 2, 8/15/94. The sample and volume information were provided by R. T. Vanderbilt Company, Inc. personnel.

The analysis for asbestos fibers consisted of fiber morphology, visual selected area electron diffraction (SAED) and elemental chemical analysis by energy dispersive spectroscopy (EDS), supplemented by the measurement and interpretation of micrographs of several selected SAED patterns. The samples were analyzed at a magnification of 1,000 X. Particles meeting the definition of a fiber > 5 μm in length, > 0.25 μm in width, and having a length to width aspect ratio ≥ 3:1 were classified as chrysotile, amphibole asbestos, amphibole cleavage, or transitional fiber.

The attached table lists each sample identification number, filter area, volume, area analyzed, asbestos fiber counts (f_s), analytical sensitivity, concentration of asbestos (f/cc), total fibers counted (F_s), and asbestos fiber ratio (f_s/F_s). Copies of the count sheets are presented in Appendix A. Each sheet contains sample information pertaining to structure identification, dimensions, magnification, filter size, and type.

RJ Lee Group, Inc. is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP), New York Department of Health Environmental Laboratory Approval Program (ELAP), and by the American Industrial Hygiene Association (AIHA). This report relates only to the items tested and shall not be reproduced except in full. NVLAP accreditation does not imply endorsement by NVLAP or any agency of the US government. These results are submitted pursuant to RJ Lee Group's current terms and conditions of sale, including the company's standard warranty and limitation of liability provisions. No responsibility or liability is assumed for the manner in which the results are used or interpreted. Unless notified in writing to return the samples covered in this report, RJ Lee Group will store the samples for a period of 30 days before discarding. A shipping and handling fee will be assessed for the return of any samples.

If you have any questions, please feel free to call me.

Sincerely,

Drew R Van Orden

Drew R. Van Orden, PE
Senior Scientist

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TEST REPORT

Asbestos Concentrations and Fiber Ratios

NIOSH 7402 Analysis

Project LSH006444-3

RJLG Sample Number	Client Sample Number	Filter Area (mm^2)	Volume (Liter)	Area Analyzed (mm^2)	Asbestos Fibers (f_s)	Analytical Sensitivity (f/cc)	Asbestos Concentration (f/cc)	Total Fibers (F_s)	Fiber Ratio (f_s/F_s)	Analysis Date
0114780HT	F-11	385	190.0	0.1155	1	0.0175	0.0175	103.5	0.01	11/16/00
0114781HT	F-12	385	300.0	0.0908	0	0.0141	< 0.0141	98.0	0	11/16/00
0114782HT	F-13	385	120.0	0.1485	0	0.0216	< 0.0216	101.5	0	11/20/00

F-11 Below mill crusher
F-12 Center mills 1, 2, 3
F-13 Over packer – NYTAL 300

Volumes provided by R. T. Vanderbilt Company, Inc. were used to calculate analytical results and sensitivities. Analytical sensitivity is calculated based on one structure in the area analyzed.

Appendix A

TEM Count Sheets

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114780HT	Grid Openings	14
Client Sample #	F-11 / Below mill crusher	Total Asbestos	1
Microscope	2000 FX	Total Non-Asbestos	102.5
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	190.0 Liters
Analyst	TWS/LH	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
1	0.5	11.00	2.00	Amphibole		X		X	Tremolite	Cleavage
1	1	20.00	3.00	Nonasbestos		X		X		TF
1	1	17.00	2.00	Nonasbestos		X		X		TF
1	1	40.00	1.10	Nonasbestos		X		X		TF
1	1	9.00	0.40	Nonasbestos		X		X		TF
1	1	11.00	1.00	Amphibole		291		29817	Tremolite	Cleavage
1	1	12.50	0.50	Nonasbestos		290		29815		TF
2	1	8.20	0.30	Nonasbestos				X		TF
2	0.5	17.00	0.60	Nonasbestos				X		TF
2	1	11.25	0.70	Nonasbestos				X		TF
2	1	7.00	0.80	Nonasbestos				X		TF
2	1	8.00	1.50	Amphibole		X		X	Tremolite	Cleavage
2	0.5	12.50	2.50	Nonasbestos		X				TF
2	0.5	7.50	0.30	Nonasbestos		X				TF
2	1	5.50	1.20	Amphibole		X		X	Tremolite	Cleavage
2	1	6.50	1.10	Amphibole		X		X	Tremolite	Cleavage
2	1	17.00	0.30	Nonasbestos		X				TF
3	1	8.25	0.80	Amphibole		X		X	Tremolite	Cleavage
3	1	11.00	0.35	Nonasbestos		X		X		TF
3	1	10.25	1.10	Amphibole		X		X	Tremolite	Cleavage
3	1	10.50	0.90	Amphibole		X		X	Tremolite	Cleavage
3	1	11.00	1.50	Amphibole		X		X	Tremolite	Cleavage
3	1	8.50	0.50	Nonasbestos				X		TF
3	1	5.20	0.90	Nonasbestos				X		TF
3	1	10.00	2.50	Nonasbestos				X		TF
3	1	6.75	0.80	Nonasbestos				X		TF
3	1	13.50	0.35	Nonasbestos				X		TF
3	1	9.50	0.30	Nonasbestos				X		TF
3	1	6.50	1.00	Nonasbestos		X				TF
4	0.5	12.00	1.10	Nonasbestos		X		X		TF
4	0.5	7.25	1.00	Amphibole		X		X	Tremolite	Cleavage
4	1	6.00	0.90	Amphibole		X		X	Tremolite	Cleavage
4	1	11.00	1.10	Amphibole		X		X	Tremolite	Cleavage
4	1	25.00	1.10	Nonasbestos				X		TF
4	1	6.00	0.40	Nonasbestos		X				TF
4	1	5.75	0.50	Nonasbestos				X		TF
4	1	10.50	1.75	Amphibole		X		X	Tremolite	Cleavage
4	1	8.50	2.00	Amphibole		X		X	Tremolite	Cleavage
5	1	5.20	0.40	Amphibole		X		X	Tremolite	Cleavage
5	1	8.50	0.60	Nonasbestos				X		TF

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114780HT	Grid Openings	14
Client Sample #	F-11 / Below mill crusher	Total Asbestos	1
Microscope	2000 FX	Total Non-Asbestos	102.5
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	190.0 Liters
Analyst	TWS/LH	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
5	0.5	22.00	0.50	Nonasbestos				X		TF
5	0.5	23.00	0.65	Nonasbestos				X		TF
5	1	10.00	0.40	Chrysotile				29822		
5	1	6.00	0.60	Nonasbestos		X				TF
5	1	9.50	1.40	Amphibole		X		X	Tremolite	Cleavage
5	1	12.50	1.50	Nonasbestos				X		TF
5	0.5	12.50	0.50	Nonasbestos		X		X		TF
5	1	10.00	2.00	Nonasbestos				X		TF
5	1	8.30	0.60	Nonasbestos				X		TF
5	1	5.40	1.25	Amphibole		X		X	Tremolite	Cleavage
6	1	10.00	3.00	Amphibole		X		X	Tremolite	Cleavage
6	1	7.00	0.80	Amphibole		X		X	Tremolite	Cleavage
6	1	10.00	2.50	Amphibole		X		X	Tremolite	Cleavage
6	1	7.25	0.40	Nonasbestos				X		TF
6	1	5.40	0.90	Nonasbestos				X		TF
7	1	22.00	1.50	Nonasbestos		X		X		TF
7	1	6.00	1.50	Amphibole		X		X	Tremolite	Cleavage
7	1	7.00	1.00	Amphibole		X		X	Tremolite	Cleavage
7	1	5.50	0.35	Amphibole		X		X	Tremolite	Cleavage
7	1	12.50	0.50	Nonasbestos	B			X		TF
7	1	7.50	0.40	Nonasbestos				X		TF
7	1	17.50	0.30	Nonasbestos				X		TF
7	1	7.00	0.20	Nonasbestos				X		TF
7	1	10.00	1.00	Nonasbestos		X		X		TF
8	1	6.50	1.40	Amphibole		X		X	Tremolite	Cleavage
8	1	7.50	0.70	Amphibole		X		X	Tremolite	Cleavage
8	1	10.00	0.30	Nonasbestos				X		TF
8	1	16.00	2.00	Amphibole		X		X	Tremolite	Cleavage
8	1	6.00	2.00	Amphibole		X		X	Tremolite	Cleavage
8	1	10.00	0.50	Nonasbestos				X		TF
8	1	5.50	0.80	Nonasbestos				X		TF
8	1	12.50	0.50	Nonasbestos				X		TF
8	1	5.50	1.00	Amphibole		X		X	Tremolite	Cleavage
9	0.5	6.50	0.70	Amphibole		X		X	Tremolite	Cleavage
9	0.5	7.00	2.00	Nonasbestos		X				TF
9	1	7.50	0.50	Nonasbestos		X				TF
10	0.5	24.00	1.00	Nonasbestos		X				TF
10	1	6.50	1.00	Amphibole		X		X	Tremolite	Cleavage
10	1	26.00	0.50	Nonasbestos				X		TF
10	1	6.00	1.20	Amphibole		X		X	Tremolite	Cleavage

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114780HT	Grid Openings	14
Client Sample #	F-11 / Below mill crusher	Total Asbestos	1
Microscope	2000 FX	Total Non-Asbestos	102.5
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	190.0 Liters
Analyst	TWS/LH	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
10	1	8.00	1.00	Amphibole		X		X	Tremolite	Cleavage
10	1	5.50	0.30	Nonasbestos				X		TF
10	1	17.00	2.00	Nonasbestos		X				TF
11	1	6.50	0.30	Nonasbestos				X		TF
11	1	7.00	0.60	Amphibole		X		X	Tremolite	Cleavage
11	1	5.50	1.00	Nonasbestos				X		TF
11	1	7.00	0.50	Nonasbestos				X		TF
11	1	6.00	0.90	Nonasbestos				X		TF
11	1	6.00	0.70	Amphibole		X		X	Tremolite	Cleavage
11	1	7.00	0.80	Nonasbestos				X		TF
12	0.5	15.00	1.50	Nonasbestos		X		X		TF
12	1	12.00	2.50	Amphibole		X		X	Tremolite	Cleavage
12	1	7.00	0.50	Nonasbestos				X		TF
12	1	18.00	2.50	Amphibole		X		X	Tremolite	Cleavage
12	1	16.00	3.00	Nonasbestos				X		TF
12	1	17.00	1.00	Nonasbestos				X		TF
12	1	19.00	0.40	Nonasbestos				X		TF
13	0.5	6.00	0.60	Nonasbestos		X				TF
13	0.5	5.50	0.60	Nonasbestos				X		TF
13	1	8.00	0.50	Nonasbestos		X		X		TF
13	1	5.50	1.00	Nonasbestos		X		X		TF
13	1	6.00	1.00	Amphibole		X		X	Tremolite	Cleavage
13	1	7.00	1.30	Amphibole		X		X	Tremolite	Cleavage
13	1	8.00	1.75	Amphibole		X		X	Tremolite	Cleavage
13	1	5.50	1.25	Amphibole		X		X	Tremolite	Cleavage
13	1	10.00	2.50	Amphibole		X		X	Tremolite	Cleavage
14	0.5	15.50	1.10	Nonasbestos		X		X		TF
14	0.5	8.00	0.45	Amphibole	M	X		X	Tremolite	Cleavage
14	1	8.00	0.60	Nonasbestos		X		X		TF
14	1	13.00	3.20	Nonasbestos		X		X		TF
14	1	18.50	2.50	Amphibole		X		X	Tremolite	Cleavage
14	1	9.00	1.75	Amphibole		X		X	Tremolite	Cleavage

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114781HT	Grid Openings	11
Client Sample #	F-12 / Center mills 1, 2, 3	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	98
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	300.0 Liters
Analyst	TWS/LH	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
1	0.5	5.75	0.50	Nonasbestos		X				TF
1	1	6.50	1.00	Nonasbestos		X				TF
1	1	8.25	0.60	Nonasbestos		296		29830		TF
1	1	17.00	1.50	Nonasbestos		295		29828		TF
1	0.5	13.00	1.20	Nonasbestos		X		X		TF
1	0.5	24.00	5.25	Amphibole		X		X	Tremolite	Cleavage
2	1	13.00	2.00	Nonasbestos		X				TF
2	1	8.25	2.00	Amphibole		X			Tremolite	Cleavage
2	1	7.50	1.90	Amphibole		X			Tremolite	Cleavage
2	1	20.00	3.50	Amphibole		X			Tremolite	Cleavage
2	1	8.50	2.00	Nonasbestos		X				TF
2	1	12.00	0.50	Amphibole		X			Tremolite	Cleavage
2	1	7.00	1.50	Amphibole		X			Tremolite	Cleavage
2	1	6.00	0.70	Amphibole		X			Tremolite	Cleavage
2	1	10.00	1.75	Amphibole		297		29832	Tremolite	Cleavage
2	0.5	6.75	0.50	Nonasbestos	M					TF
3	1	6.00	0.50	Nonasbestos				X		TF
3	0.5	6.50	0.45	Nonasbestos				X		TF
3	1	8.50	1.50	Amphibole		X			Tremolite	Cleavage
3	1	6.25	1.20	Amphibole		X			Tremolite	Cleavage
3	1	9.00	1.00	Nonasbestos				X		TF
3	0.5	5.25	0.40	Nonasbestos	M			X		TF
3	0.5	19.00	0.50	Nonasbestos	M			X		TF
3	1	13.50	1.00	Nonasbestos		X				TF
4	1	8.50	2.00	Nonasbestos		X		X		TF
4	1	11.50	2.00	Nonasbestos		X		X		TF
4	1	37.00	2.00	Nonasbestos		X		X		TF
4	1	7.00	0.50	Nonasbestos		X		X		TF
4	1	7.00	1.00	Nonasbestos		X		X		TF
4	1	6.00	1.00	Amphibole		X		X	Tremolite	Cleavage
4	1	6.00	1.00	Nonasbestos		X		X		TF
4	1	8.00	1.00	Nonasbestos		X		X		TF
4	1	8.00	2.00	Amphibole		X		X	Tremolite	Cleavage
4	1	8.50	1.50	Nonasbestos		X		X		TF
4	1	7.50	0.40	Nonasbestos		X		X		TF
4	1	23.00	3.00	Nonasbestos		X		X		TF
4	1	6.50	1.20	Nonasbestos		X		X		TF
5	1	10.00	0.30	Nonasbestos		X		X		TF
5	1	10.00	2.00	Amphibole		X		X	Tremolite	Cleavage
5	1	22.00	0.90	Nonasbestos		X		X		TF

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114781HT	Grid Openings	11
Client Sample #	F-12 / Center mills 1, 2, 3	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	98
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	300.0 Liters
Analyst	TWS/LH	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
5	1	9.00	0.50	Amphibole		X		X	Tremolite	Cleavage
5	1	17.00	5.00	Nonasbestos		X		X		TF
5	1	9.00	0.50	Nonasbestos		X		X		TF
5	1	15.00	2.00	Amphibole		X		X	Tremolite	Cleavage
5	1	5.40	0.30	Nonasbestos		X		X		TF
5	1	47.00	2.50	Nonasbestos		X		X		TF
6	1	16.00	0.30	Nonasbestos		X		X		TF
6	1	8.50	0.50	Nonasbestos		X		X		TF
6	1	15.00	2.00	Amphibole		X		X	Tremolite	Cleavage
6	1	14.00	1.00	Nonasbestos		X		X		TF
6	1	5.50	1.00	Amphibole		X		X	Tremolite	Cleavage
6	1	21.50	1.00	Nonasbestos		X		X		TF
6	1	7.00	0.50	Amphibole		X		X	Tremolite	Cleavage
6	1	5.20	0.30	Nonasbestos		X		X		TF
7	1	11.00	1.50	Amphibole		X		X	Tremolite	Cleavage
7	1	5.50	0.60	Nonasbestos		X		X		TF
7	1	5.10	0.80	Amphibole		X		X	Tremolite	Cleavage
7	1	9.00	1.00	Amphibole		X		X	Tremolite	Cleavage
7	1	9.00	1.50	Amphibole		X		X	Tremolite	Cleavage
7	1	6.00	0.40	Nonasbestos		X		X		TF
7	1	15.00	1.30	Nonasbestos		X		X		TF
8	0.5	15.50	0.50	Nonasbestos		X		X		TF
8	1	9.50	1.00	Nonasbestos		X		X		TF
8	1	5.50	0.60	Nonasbestos		X		X		TF
8	1	8.50	2.00	Nonasbestos		X		X		TF
8	1	7.50	1.00	Nonasbestos		X		X		TF
8	1	10.00	1.50	Nonasbestos		X		X		TF
8	1	8.00	2.50	Nonasbestos		X		X		TF
8	1	15.00	3.00	Nonasbestos		X		X		TF
9	0.5	6.00	0.50	Nonasbestos		X		X		TF
9	1	10.50	1.00	Nonasbestos		X		X		TF
9	1	5.20	0.60	Nonasbestos		X		X		TF
9	1	23.50	0.50	Nonasbestos		X		X		TF
9	1	23.00	3.20	Amphibole		X		X	Tremolite	Cleavage
9	1	6.50	1.50	Nonasbestos		X		X		TF
9	1	6.00	0.40	Amphibole		X		X	Tremolite	Cleavage
9	1	8.00	0.50	Nonasbestos		X		X		TF
9	1	7.50	1.00	Nonasbestos		X		X		TF
9	1	8.00	0.90	Nonasbestos		X		X		TF
9	1	6.00	1.90	Amphibole		X		X	Tremolite	Cleavage

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114781HT	Grid Openings	11
Client Sample #	F-12 / Center mills 1, 2, 3	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	98
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	300.0 Liters
Analyst	TWS/LH	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
9	1	7.50	1.50	Amphibole		X		X	Tremolite	Cleavage
10	0.5	15.50	1.50	Nonasbestos		X		X		TF
10	1	8.00	0.30	Nonasbestos		X		X		TF
10	1	5.20	0.80	Nonasbestos		X		X		TF
10	1	9.00	0.40	Nonasbestos		X		X		TF
10	1	16.00	2.00	Nonasbestos		X		X		TF
10	1	21.00	1.00	Nonasbestos		X		X		TF
10	1	6.00	0.70	Nonasbestos		X		X		TF
10	1	7.00	0.60	Amphibole		X		X	Tremolite	Cleavage
10	1	18.00	2.50	Nonasbestos		X		X		TF
10	1	7.50	1.00	Nonasbestos		X		X		TF
11	1	6.00	0.80	Nonasbestos		X		X		TF
11	1	20.00	6.00	Nonasbestos		X		X		TF
11	1	7.50	0.60	Amphibole		X		X	Tremolite	Cleavage
11	1	5.50	1.00	Nonasbestos		X		X		TF
11	1	9.00	2.00	Amphibole		X		X	Tremolite	Cleavage
11	1	8.00	2.00	Amphibole		X		X	Tremolite	Cleavage
11	1	6.00	0.50	Nonasbestos		X		X		TF
11	1	6.50	2.00	Amphibole		X		X	Tremolite	Cleavage
11	1	6.00	1.50	Amphibole		X		X	Tremolite	Cleavage
11	1	8.20	0.30	Nonasbestos		X		X		TF
11	1	28.50	0.70	Nonasbestos		X		X		TF
11	1	5.50	0.70	Nonasbestos		X		X		TF

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114782HT	Grid Openings	18
Client Sample #	F-13 / Over packer – NYTAL 300	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	101.5
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	120.0 Liters
Analyst	TWS/BF	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
1	0.5	6.00	1.30	Amphibole		X		X	Tremolite	Cleavage
1	0.5	9.50	2.00	Nonasbestos		X		X		TF
1	1	10.25	2.20	Amphibole		X		X	Tremolite	Cleavage
1	0.5	9.00	1.50	Nonasbestos		X		X		TF
1	1	7.50	0.70	Nonasbestos		299		29836		TF
1	1	8.00	2.00	Amphibole		X		X	Tremolite	Cleavage
1	1	7.25	1.75	Amphibole		298		29834	Tremolite	Cleavage
1	0.5	6.25	1.10	Amphibole		X		X	Tremolite	Cleavage
1	1	9.00	0.80	Nonasbestos		X		X		TF
1	1	12.00	2.50	Nonasbestos		X		X		TF
2	0.5	7.00	0.50	Amphibole		X			Tremolite	Cleavage
2	1	10.00	2.40	Nonasbestos		X				TF
2	1	7.25	1.10	Amphibole				X	Tremolite	Cleavage
2	0.5	5.25	0.30	Nonasbestos	M			X		TF
2	1	5.50	0.60	Nonasbestos		X				TF
2	1	6.75	1.30	Amphibole		X			Tremolite	Cleavage
2	0.5	11.00	0.50	Nonasbestos		X		X		TF
2	1	14.50	3.00	Nonasbestos		X		X		TF
2	1	6.00	1.10	Amphibole		X		X	Tremolite	Cleavage
2	1	16.00	1.80	Nonasbestos		X		X		TF
3	1	8.50	1.50	Amphibole				X	Tremolite	Cleavage
3	1	8.00	2.00	Amphibole				X	Tremolite	Cleavage
3	1	8.25	1.10	Amphibole				X	Tremolite	Cleavage
3	1	11.50	0.35	Nonasbestos				X		TF
3	1	7.00	0.50	Nonasbestos				X		TF
4	1	10.50	1.30	Amphibole				X	Tremolite	Cleavage
4	1	8.00	0.80	Nonasbestos		X		X		TF
4	1	7.50	0.80	Amphibole				X	Tremolite	Cleavage
4	1	5.25	0.60	Amphibole				X	Tremolite	Cleavage
4	1	35.00	5.00	Amphibole		X			Tremolite	Cleavage
4	1	21.00	2.20	Nonasbestos		X		X		TF
4	1	8.00	0.90	Amphibole				X	Tremolite	Cleavage
5	0.5	7.00	0.90	Amphibole		X			Tremolite	Cleavage
5	1	7.00	0.80	Nonasbestos				X		TF
5	1	6.50	1.00	Nonasbestos				X		TF
5	1	11.50	0.50	Nonasbestos				X		TF
5	0.5	20.00	5.00	Amphibole		X			Tremolite	Cleavage
5	1	11.50	0.40	Nonasbestos				X		TF
6	1	11.00	1.00	Amphibole				X	Tremolite	Cleavage
6	1	12.50	3.00	Amphibole		X			Tremolite	Cleavage

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114782HT	Grid Openings	18
Client Sample #	F-13 / Over packer – NYTAL 300	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	101.5
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	120.0 Liters
Analyst	TWS/BF	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
6	0.5	10.25	0.40	Nonasbestos				X		TF
6	1	5.50	1.00	Nonasbestos				X		TF
6	1	7.00	1.50	Nonasbestos		X				TF
6	1	18.00	1.50	Amphibole				X	Tremolite	Cleavage
6	0.5	5.75	0.90	Nonasbestos				X		TF
6	1	7.00	0.50	Nonasbestos				X		TF
7	1	8.50	1.75	Amphibole				X	Tremolite	Cleavage
7	1	7.75	0.40	Nonasbestos				X		TF
7	1	5.75	0.50	Nonasbestos				X		TF
7	1	9.75	0.75	Nonasbestos				X		TF
8	1	7.50	0.60	Nonasbestos				X		TF
8	1	8.00	0.75	Nonasbestos				X		TF
8	1	8.50	0.40	Nonasbestos				X		TF
9	0.5	10.50	0.80	Amphibole				X	Tremolite	Cleavage
9	0.5	6.50	1.50	Amphibole				X	Tremolite	Cleavage
9	0.5	9.00	0.45	Nonasbestos				X		TF
9	1	18.00	1.00	Amphibole				X	Tremolite	Cleavage
9	1	5.75	0.90	Amphibole				X	Tremolite	Cleavage
9	1	5.50	0.90	Amphibole		X		X	Tremolite	Cleavage
9	1	6.50	0.80	Nonasbestos				X		TF
10	0.5	6.00	1.00	Nonasbestos				X		TF
10	1	5.50	1.00	Amphibole				X	Tremolite	Cleavage
10	1	9.50	1.00	Nonasbestos				X		TF
11	1	6.50	1.80	Amphibole		X		X	Tremolite	Cleavage
11	1	12.50	0.50	Nonasbestos				X		TF
12	1	6.50	0.80	Nonasbestos				X		TF
12	1	5.20	0.60	Amphibole		X		X	Tremolite	Cleavage
12	1	6.80	1.00	Amphibole		X		X	Tremolite	Cleavage
12	1	7.00	0.40	Nonasbestos		X		X		TF
12	1	20.00	3.00	Amphibole		X		X	Tremolite	Cleavage
13	0.5	19.00	2.50	Amphibole		X		X	Tremolite	Cleavage
13	1	5.20	0.50	Amphibole				X	Tremolite	Cleavage
13	1	5.50	0.80	Amphibole				X	Tremolite	Cleavage
13	1	16.00	1.50	Nonasbestos	B			X		TF
13	1	6.10	0.60	Amphibole		X		X	Tremolite	Cleavage
14	1	7.00	1.00	Nonasbestos				X		TF
14	1	7.30	0.70	Nonasbestos		X		X		TF
14	1	9.30	1.00	Amphibole				X	Tremolite	Cleavage
14	1	7.00	1.00	Nonasbestos		X		X		TF
14	1	6.00	0.80	Amphibole		X		X	Tremolite	Cleavage

RJ Lee *Group*, Inc.
Count Sheet

Client Name	R. T. Vanderbilt Company, Inc.		
Project Number	LSH006444-3	RJLG QA Number	HQ18755
RJLG Sample #	0114782HT	Grid Openings	18
Client Sample #	F-13 / Over packer – NYTAL 300	Total Asbestos	0
Microscope	2000 FX	Total Non-Asbestos	101.5
Accelerating Voltage	120 Kv	Filter	CE 385 mm^2
Magnification	1,000 X	Volume	120.0 Liters
Analyst	TWS/BF	Grid Opening Area	0.0083 mm^2
EDS Disk		Dilution Factor	1

Field	Fiber	Length µm	Width µm	Structure Type	Morph	EDS	Photo	SAED	Amphibole Type	Comment
14	1	6.50	1.00	Amphibole		X		X	Tremolite	Cleavage
14	1	9.90	2.20	Amphibole		X		X	Tremolite	Cleavage
15	1	15.00	2.00	Amphibole				X	Tremolite	Cleavage
15	1	9.50	2.30	Amphibole				X	Tremolite	Cleavage
15	1	16.00	2.00	Amphibole		X		X	Tremolite	Cleavage
15	1	6.00	0.60	Amphibole		X		X	Tremolite	Cleavage
15	1	14.00	1.60	Amphibole		X		X	Tremolite	Cleavage
15	1	5.20	1.00	Nonasbestos				X		TF
15	1	6.50	1.50	Nonasbestos		X		X		TF
15	1	8.50	1.60	Nonasbestos		X		X		TF
16	0.5	10.40	0.60	Nonasbestos				X		TF
16	0.5	7.30	1.20	Amphibole				X	Tremolite	Cleavage
16	0.5	18.50	3.50	Amphibole		X		X	Tremolite	Cleavage
16	0.5	7.00	0.40	Amphibole		X		X	Tremolite	Cleavage
16	0.5	9.00	1.40	Amphibole				X	Tremolite	Cleavage
16	1	5.20	0.50	Nonasbestos				X		TF
16	1	6.30	1.20	Amphibole				X	Tremolite	Cleavage
16	1	6.50	0.50	Amphibole				X	Tremolite	Cleavage
16	1	8.00	2.00	Nonasbestos				X		TF
17	0.5	15.00	2.00	Nonasbestos		X		X		TF
17	1	6.00	0.40	Amphibole				X	Tremolite	Cleavage
17	1	5.50	0.60	Nonasbestos		X		X		TF
17	1	7.00	0.50	Nonasbestos				X		TF
17	1	7.50	1.00	Amphibole				X	Tremolite	Cleavage
17	1	9.50	0.60	Nonasbestos		X				TF
17	1	7.00	1.00	Amphibole				X	Tremolite	Cleavage
17	1	6.00	0.26	Amphibole				X	Tremolite	Cleavage
17	1	9.00	0.60	Amphibole				X	Tremolite	Cleavage
18	0.5	6.00	0.60	Nonasbestos	B			X		TF
18	1	14.00	0.90	Amphibole				X	Tremolite	Cleavage
18	1	6.50	0.60	Amphibole				X	Tremolite	Cleavage
18	1	7.0	0.40	Nonasbestos				X		TF
18	1	14.00	1.10	Nonasbestos		X		X		TF