Erskine Environmental Consulting

Geologic Investigations Hazardous Materials Naturally Occurring Asbestos

February 13, 2020

Subject: Response to Earthres letter dated January 30, 2020 by Louis F. Vittorio, P.G. "*Comments dated December 23, 2019, from Steve Baluh, P.E. Regarding the "Qualitative Geologic Survey Report" dated November 15, 2019 Rock Hill Quarry (Pierson Materials/Hanson Aggregates) East Rockhill Township, Bucks County, PA*"

The following is a response to EARTHRES' comments on the letter by Steve Baluh, P.E., referenced above. Many of EARTHRES' comments focus on subjects and opinions that originated in EEC's previous submittals, and therefore, inaccuracies, misstatements and unsupported conclusions that are present throughout the document require comment by EEC.

The comments are generally presented in the order presented in the EARTHRES document.

Page 1, Introduction.

EARTHRES dismisses comments by Mr. Baluh because as a Professional Engineer, he is "*not a geologist*" and providing comments on "*topics well outside his area of professional practice*". It should be noted that there are areas of professional discipline in the fields of geology and engineering that overlap and require cross disciplinary education and experience. For example, California requires a license to provide services related to these fields as well as use the title of Certified Engineering Geologist (CEG) or Geotechnical Engineer (GE).

EARTHRES has a point where asbestos mineralogy and testing is concerned. The test methods that are referenced by the R.J. Lee Group (RJLG) were originally developed for building materials where a very narrow group comprised of six asbestos minerals were applied. As a result, these minerals are relatively easy to distinguish from one another, and it is possible for laboratory technicians without a geology degree to be trained sufficiently to apply the prescriptive test methods to building materials.

However, Naturally Occurring Asbestos (NOA) is a different matter altogether, and the field sampling and laboratory analysis requires the expertise of an experienced degreed geologist who, through many hours of coursework including field mapping, mineralogy, optical mineralogy, petrography, metamorphism, and rock and mineral fabrics and textures, can adequately analyze the occurrence, composition, and textures of minerals in the complex geologic setting. The National Sand, Stone, and Gravel Association (NSSGA) agrees: NSSGA's Mineral Identification and Management Guide states in its Appendix A, Identification of Protocol Mineral Fibers: "*This analysis will be conducted by a geologist who has earned at least a BS and MS degrees in geology and with specific education and/or training in optical mineralogy*".

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As the company whose project geologist is responsible for validating the entire geologic investigation, including the selection of test methodology and interpretation of results, EARTHRES appears to defer to Mr. Van Orden of RJLG on subjects involving mineralogy, who, ironically, is a Registered Professional Engineer. By EARTHRES' own reckoning, Mr. Van Orden is commenting on "*topics well outside his area of professional practice*".

EEC does not fully agree with this position, but does agree that responses to comments should focus on the merit of the comment, and not distract attention by questioning the qualifications or intent of the commenter.

Pages 2-4, Comments Regarding the Qualitative Geologic Survey Report (QGSR).

EARTHRES provided many responses in defense of its QGSR. However, as indicated in EEC's previous reviews of the Qualitative Geologic Survey Sampling Plan (QGSSR) that was the basis for the investigation, there is ample evidence that the *Qualitative* investigation was compromised from the beginning, and no amount of testing or re-testing can mitigate its deficiencies. For example, the original QGSSP dated April 3, 2019 included a field screening tool to direct sampling:

"Found mineral veins will be examined using a hand lens and fine steel pick to assess the presence of fibrous mineral morphology. If potentially suspect mineral morphology is identified, the mineral veining will be photographed and sampled in the following manner…"

In its June 6, 2019 review of the QGSSP, EEC pointed out that the practice of field screening to direct sampling for asbestos is inappropriate and beneath any Standard of Practice for a Professional Geologist performing NOA investigations.

EEC also questioned the validity of a Qualitative assessment, and encouraged EARTHRES to revise the Qualitative plan to a level that meets the Standard of Practice for Professional Geologists. This comment was not accepted, and the April 3rd Qualitative Plan was implemented as originally designed.

This raises three questions:

1. What other techniques that direct sampling away from rocks that may contain asbestos were employed to produce the Qualitative report?
2. Can the PA DEP and Rock Hill Township residents have confidence in and rely on data produced during a Qualitative survey?
3. Why wasn't a proper Quantitative survey conducted in the first place?

The Qualitative techniques appear to have an origin within the assessment protocols found in the NSSGA Mineral Identification and Management Guide ("Identification Guide"). The identification Guide also allows for an arbitrary field assessment of whether or not a rock unit may or may not be comprised of "Protocol Fibers", and the EARTHRES response reiterates this.

Protocol Fibers are defined as asbestiform fibers, a subjective and imprecise term that cannot be used in the field, and there is no protocol for its determination in any test method that is relevant to the Rockhill Quarry project. As will be discussed below, EPA does not differentiate between fibers based on perceived crystallization morphology or habit, and OSHA recently has abandoned the term for its testing and reporting procedures. Further, RJLG appears to eliminate fibers, on a fiber by fiber basis, those that have tips which are not exhibiting an ideal morphology. This protocol appears to be based on RJLG's unique, unpublished and incorrect characterization of regulated asbestos. The overall plan and its implementation through its design removes fibers from reporting that would otherwise be reported, resulting in an under reporting of asbestos and miscommunication of potential risk to offsite residents.

The Qualitative basis of the investigation and testing procedures allows for sampling and testing procedures to deviate from normal industry practices, test method protocols, and current regulatory guidance. Based on the comments in the EARTHRES document, EEC's recommendation remains unchanged: PA DEP should contract directly with a Professional Geologist and experienced testing laboratory to conduct an unbiased investigation based on current Standard of Practice. The geologist and laboratory should have an appropriate body of experience with NOA, and neither should have a significant relationship with the mining industry.

Page 4 (bottom): Comment on the Definition of Asbestos

EARTHRES refers to a previous document submitted by RJLG and states that Hanson and RJLG "*has provided clear and unambiguous NOA terminology, definitions, and corresponding regulation references, including US EPA definitions pertaining to asbestos. Also provided were the appropriate definitions and regulations for asbestos as additionally regulated by the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA), as well as the appropriate analytical methods to be used for asbestos analysis".*

These "definitions" are general descriptions of asbestos that was mined commercially, but are not incorporated into the test methods for good reason. The subjective interpretation of these terms and subsequent development of procedures that significantly deviate from the test method procedures is inappropriate. RGLG has indicated that it does not have an SOP to apply these deviations. Therefore, the test results cannot be validated as accurate, precise, and reproducible.

Two documents by EPA and OSHA have recently been released that illustrates the current viewpoint of these agencies. In both cases, differential counting procedures are not allowed. Each are summarized below, and are attached as appendices to this review.

Executive Summary, Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc.

On January 6, 2020, the Interagency Working Group on Asbestos in Consumer Products (IWGACP) released an executive summary of its review of test methodologies as they apply to the analysis of naturally occurring asbestos to support the development of standardized testing methods for asbestos and other mineral particles of health concern in talc that could potentially affect consumer product safety[1]. The working group included representatives of EPA, OSHA, NIOSH, the USGS and other Federal agencies[2].

This document (see Appendix A) was discussed in detail in the EEC memorandum dated January 21, 2020, and EEC refers the reader to that document. However, four conclusions that are particularly relevant to the "definition" issue are restated below (see number (3) for the definition of EMP and its purpose to resolve the "asbestos vs. non-asbestos ambiguity):

1. *"Both types of elongate minerals (asbestiform habit and non-asbestiform habit) are suspected of having biological activity with similar pathological outcomes. Therefore, the distinction is irrelevant".*

2. *"Countable EMPs have an aspect ratio (AR) of >3:1 and a length of > 0.5 µm using the most inclusive criteria for length and AR from among the "asbestos" counting rules in established testing protocols. Testing laboratories should report all EMPs having length ≥ 0.5 µm (500 nm)".*

3. *"Adoption of the term EMP as "any mineral particle with a minimum aspect ratio of 3:1", consistent with how this term is defined in the NIOSH Bulletin 62, to resolve ambiguity and disagreement in mineral (asbestos versus non-asbestos) identification."*

4. *"Although IWGACP concludes that criteria for differential counting and classification of EMPs would be beneficial, no specific recommendations were agreed upon during deliberations. Therefore, at this time the IWGACP recommends reporting and counting all EMPs of covered minerals under a single classification with additional information that would allow further classification based on measurements such as mineral type and dimensions in the future".*

It appears clear that EPA, OSHA, NIOSH, USGS and other regulatory agencies do not subscribe to using the general definitions of "asbestos" as a method to differentiate particles from reporting requirements, and no form of differential counting should be used as a basis to remove fibers from reporting.

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[1] Executive Summary: Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc, dated January 6, 2020.

[2] Food and Drug Administration (FDA), National Institute for Occupational Safety and Health (NIOSH), National Institute of Health (NIH)/ National Institute of Environmental Health Sciences (NIEHS), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), the National Institute of Standards & Technology (NIST), and the U.S. Geological Survey (USGS).

OSHA Report of Evaluation of Cosmetics and Cosmetic Talc for FDA, 23 February 2019.

In 2019, and in support of the test method recommendations discussed above, OSHA conducted an evaluation of naturally occurring asbestos (termed “EMPs) in talc deposits and products. This included “naturally occurring asbestos” in mines where talc has been extracted and cosmetic products where NOA is present as a natural byproduct. Several photographs where tremolite (the magnesium member of the actinolite-tremolite solid solution group) was identified as asbestos are shown in Figures 1 through 4. The photographs illustrate OSHA’s current viewpoint regarding the determination of whether or not a fiber should be reported as asbestos. The entire text is attached as Appendix B.

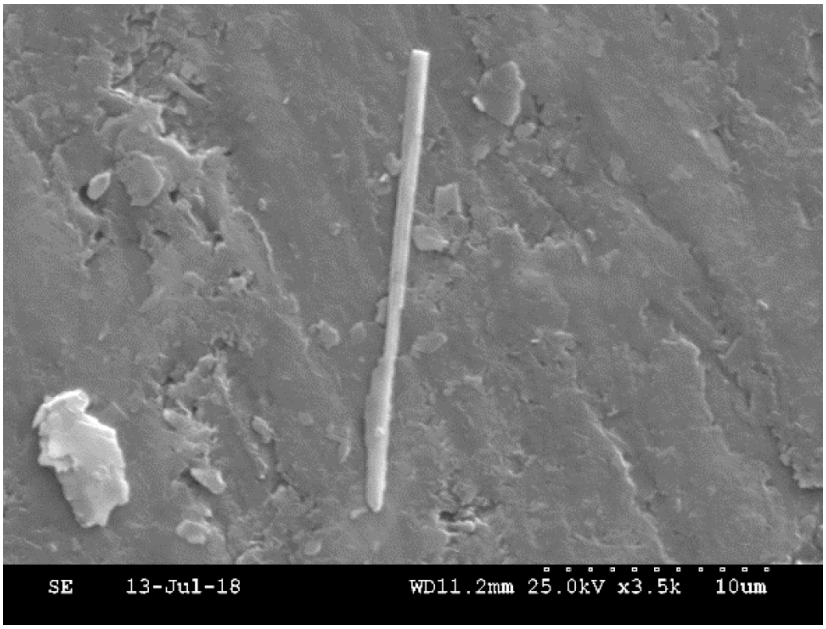

Figure 1: Sample 761227: Tremolite Asbestos

RJLG uses stepping sides and non-orthogonal fiber tips as criteria to identify a fiber as non-asbestos and eliminate it from reporting. This fiber has stepping, and the lower tip is pointed and not at right angles Orthogonal) to the fiber. Also, the fiber is not curved and has no splayed ends. It is also approximately 1 µm wide, well above the 0.1 µm average width that OSHA cites as typical for an asbestos fibril. However, OSHA considers this fiber as asbestos, in spite of the general description or definition of asbestos in its test method used by RJLG.

Figure 2: Sample 761230: Tremolite Asbestos

This fiber has stepped margins, pointed tips, is not curved, and does not possess splayed ends. It is also about 1µm wide, well above the 0.1 µm average width that OSHA cites as typical for an asbestos fibril. However, OSHA considers this fiber as asbestos, in spite of the general description or definition of asbestos in its test method used by RJLG.

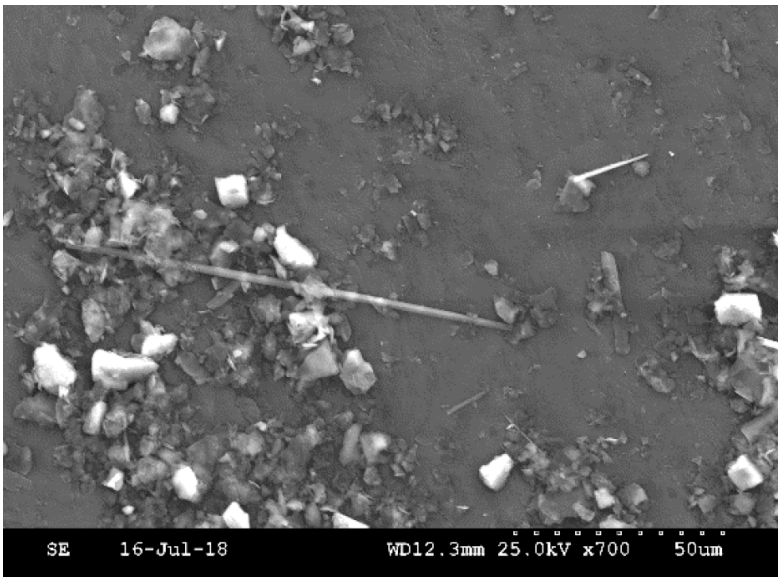

Figure 3: Sample 761231: Tremolite Asbestos

This fiber has tips that are not perpendicular to the fiber, and is approximately 2 µm wide, well above the 0.1µm average width that OSHA cites as typical for an asbestos fibril. However, OSHA considers this fiber as asbestos, in spite of the general description or definition of asbestos in its test method used by RJLG.

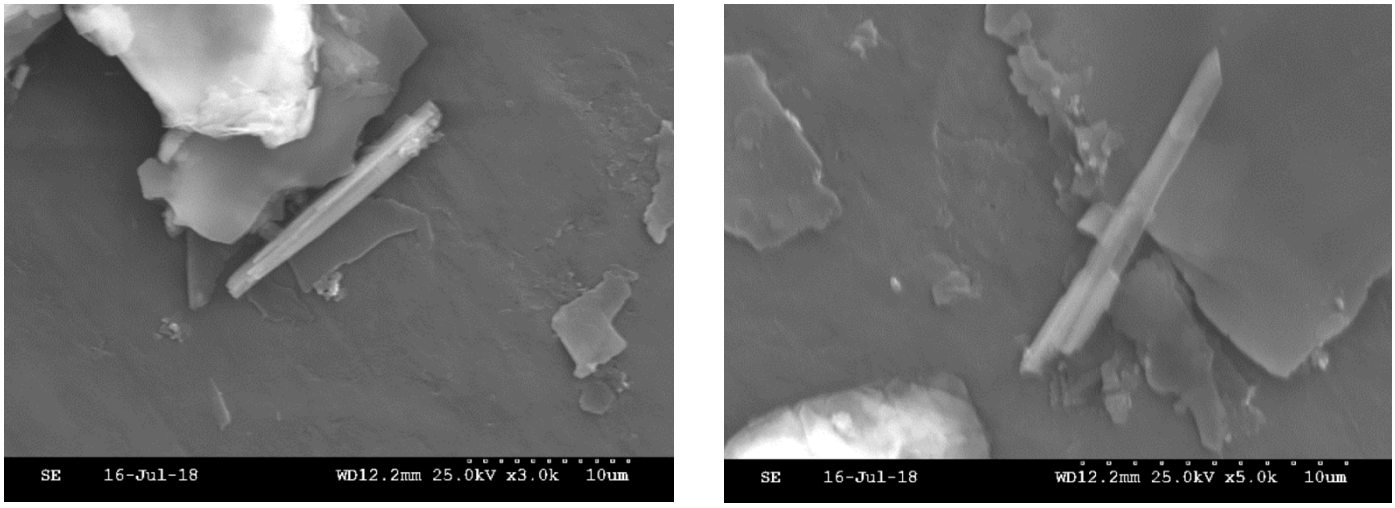

Figure 4: Sample 1027488: Tremolite Asbestos

These fibers show stepped sides, sides that are sub-parallel, have pointed tips, are not curved, do not exhibit splayed ends. They are also greater than 1.5µm wide, well above the 0.1 µm average width that OSHA cites as typical for an asbestos fibril. However, OSHA considers this fiber as asbestos, in spite of the general description or definition of asbestos in its test method used by RJLG.

Other fibers in the study were eliminated on the basis of a positive identification as talc, or a chemistry that is not consistent with amphiboles.

It is important to note that OSHA clarifies its definition asbestiform and requirements of a countable fiber as follows:

- "*The term "asbestiform" is not a growth habit. It is a description of a mineral which has a fibrous growth habit. The growth habit used in mineralogy is "fiber."*

- *A regulatory fiber is a fiber of asbestos:*

    - *Having an aspect ratio greater than or equal to 3:1*
    - *Longer than or equal to 5 micrometers*
    - *Visible in a phase contrast microscope (PCM)*

In this case, these criteria are equivalent to the current counting rules for air samples that have been applied by OSHA since its formation in the early 1970's. The Permissible exposure Limit of 0.1 fibers per cc of air is based on these counting rules, and not related to its general definition of asbestiform, as RJLG argues is allowed and uses to deviate from test methods. EPA has a different set of counting rules depending on the applicability of the test methods. There is no allowance in the test methods to deviate from the counting rules, and this is central to EEC's argument that RJLG's protocols are inappropriate and under report asbestos.

Page 6: Comment Regarding EPA's Approval to Use Differential Counting Methods at the Sparta Site.

EARTHRES stated, using text provided by Mr. Van Orden of RJLG: *"The procedures used by RJLG to differentiate asbestiform amphibole from their non asbestiform counterparts was approved for use by the EPA in the study conducted at the Sparta, NJ quarry".*

As was discussed in the memorandum dated January 21, 2010, EEC discussed at length why this statement is not correct. The report that RJLG referred to states: "*For risk assessment, the approach proposed in a new protocol (Berman and Crump 2001) was adopted for this study*".

The EPA/Berman study used the Berman and Crump protocol, and then compared it to the standard EPA methodology. At that time, this new proposed EPA method was under peer review, and the Sparta quarry project offered a test case.

According to Dr. Berman, a data set provided by RJLG, based on an internal procedure, was applied to both methods for comparison. Dr. Berman stated that the data set was provided upon request, presumably by RJLG.

The comparison was just that- a comparison, and not an approval by EPA. It turns out that the RJLG differential counting approach led to an underestimation of risk by a factor of six, showing that it eliminated asbestos fibers that contribute to cancer risk. Figure 4 compares the risk calculated risk using the RJLG protocol to the risk calculated using the EPA protocol. The graph speaks for itself: the application of the RJLG protocol is neither precise, accurate, nor reproducible.

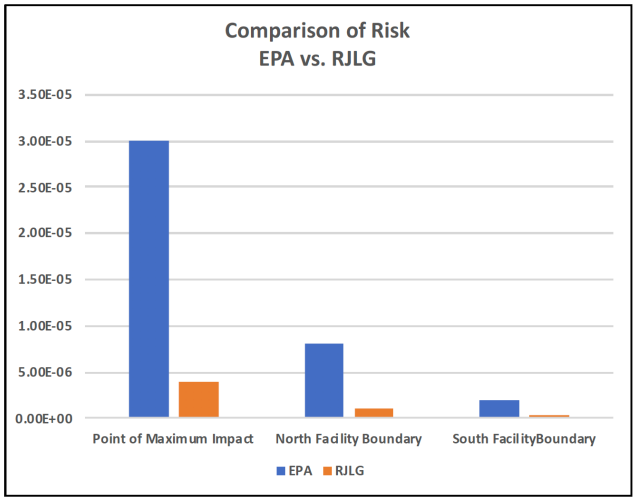

Figure 4: Comparison of calculated risk between the EPA protocol and EPA protocol using RJLG differential counting[3].

[3] *Berman and Crump, 2003, "Analysis and interpretation of measurements for the determination of asbestos in core samples collected at the Southdown Quarry in Sparta, New Jersey", Report of analysis, Aeolus, Inc., November 12, 2003.*

Page 6: Comment Regarding Acceptance of the RJLG Protocol at the El Dorado Hills project.

EARTHRES states, using text provided by Mr. Van Orden of RJLG: *"EPA Region 9 did criticize our data evaluation of their El Dorado analyses. RJLG responded to that criticism with extensive notes and data documenting techniques, definitions, and procedures – all of which have been accepted by the EPA since there was no further response from them.*"

EARTHRES and RJLG appear to be claiming EPA acceptance as follows:

- EPA conducted a major study at the El Dorado Hills site in accordance with its standard practices and techniques,
- RJLG responds, stating that EPA's methods are incorrectly applied to NOA, based on the differential counting procedures that are the core of controversy at the Rockhill quarry site,
- EPA responds with language that is more of an admonishment, concluding: "*The R. J. Lee Report draws conclusions that are contradicted by the El Dorado Hills data and by generally accepted scientific principles for measuring asbestos exposure*",
- RJLG responds (as reported by EARTHRES) with a new set of arguments,
- EPA does not respond to this second round of arguments,
- Therefore, RJLG determines that a lack of response constitutes an approval and reversal of EPA's conclusion.

EPA made its position quite clearly, and in EEC's opinion, had no reason to enter in to what can become an endless comment-response cycle. RJLG's attempt to relitigate a final decision by EPA does not constitute an approval, and the conclusions stand.

Page 7: Comment Regarding the Absence of an EPA Water Method for non-potable water.

EARTHRES states: "*There is no promulgated US EPA method for non-potable water (regardless of the source)".*

This statement is not correct, and in fact, is refuted by RJLG itself (see Figure 5).

Figure 5: Partial screen shot of RJLG's web page that refutes the claim that there is no EPA method for asbestos in potable water (screen shot taken on February 7, 2020).

It should be noted that the schedule of analyses is incorrect. EPA 100.1 is applied to non-potable water, and EPA 100.2 is applied to drinking water.

Page7: Comment Regarding the Elimination of Fibers that are <5µm.

EARTHRES stated, using text provided by Mr. Van Orden of RJLG, that: "*RJLG re-analyzed the water samples looking for the asbestos fibers that RJLG knows are appropriate for various inhalation risk models, which are fibers 5 µm and longer*".

EARTHRES and RJLG further states:

"*Analysis of materials should be targeted toward those fibers that have been shown to cause an increase in risk, hence the use of the minimum length of 5 µm for the non-potable water analyses*."

It is inappropriate to modify a test method by incorporating general definitions to modify the test method, and even more inappropriate to apply counting rules from one test method to another. It is fully unacceptable to incorporate methods from a separate discipline and modify a test method that is not intended to be used by that discipline. In this case, health risk assessments are conducted using air data, specifically using Phase Contrast Microscopy. Data from soil and rock is used for a completely different purpose.

This concept is clearly specified in the document that EARTHRES cited as a basis: *Asbestos; CASRN 1332-21-4*. This document states:

"The unit risk is based on fiber counts made by phase contrast microscopy (PCM) and should not be applied directly to measurements made by other analytical techniques".

It would be increasingly unacceptible if a sample analyzed using differential counting methods was applied for health risk determinations, because the risk assessor would be handed a "broken deck" of data. This was proven in the Berman study, discussed above, where the broken deck led to an under estimation of risk by a factor of six.

The comments and conclusions provided in this memorandum represents the opinion of the author, and is based on more than 33 years of experience in the fields of asbestos consulting and testing. It is suggested that the RJLG and others review this document, and offer their opinions or rebuttal to the material provided herein. EEC will be happy to review and comment on any submittal.

Please contact me if you have any questions.

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Appendix A

Executive Summary, Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc.

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EXECUTIVE SUMMARY[1]

PRELIMINARY RECOMMENDATIONS ON TESTING METHODS FOR ASBESTOS IN TALC AND CONSUMER PRODUCTS CONTAINING TALC

January 6, 2020

In the fall of 2018, the United States Food and Drug Administration (US FDA) formed the Interagency Working Group on Asbestos in Consumer Products (IWGACP), with representatives from eight federal agencies[2], to support the development of standardized testing methods for asbestos and other mineral particles of health concern in talc that could potentially affect consumer product safety.[3] The IWGACP was formed in response to reports of the presence of asbestos in talc-containing cosmetic products, with talc being the presumptive source of asbestos. Since 2017, there have been several voluntary recalls of cosmetic products by retailers in the US and globally (Canada, Netherlands, Taiwan) due to the presence of asbestos.

Talc is a hydrated magnesium silicate mineral that is used in a wide variety of consumer products including cosmetics, foods, dietary supplements, drugs, medical devices, ceramics, and art materials. Raw material talc is obtained from mines that may also contain asbestos and related minerals. Removal of asbestos by purification of talc ores is extremely difficult. Thus, judicious selection of talc deposits and mining locations within the deposits is necessary to avoid contamination with asbestos and similar biologically active mineral particles. It is imperative that appropriate monitoring methods are available to detect asbestos in talc to ensure its suitability as a raw material for use as an ingredient in consumer products.

The health hazards associated with asbestos are well documented. There is general agreement among US federal agencies, most developed nations, and the World Health Organization (WHO) that there is no known safe level of asbestos exposure. Inhalation of asbestos, from any source, is a safety concern because it can cause the formation of scar-like tissue in the lung, resulting in

[1] The recommendations and opinions expressed in this document are based on discussions on matters of "scientific debate" (contentious issues that have not been completely resolved or finalized in the ongoing debate) among subject matter experts on the IWGACP and do not necessarily reflect the opinions or policies of their agencies. These recommendations do not represent proposed changes to any regulations of the U.S. Government. The use of the terms "IWGACP" or "we" refers to the consensus opinion of the working group scientists and not the individual experts or the agencies they represent.

[2] Food and Drug Administration (FDA), National Institutes for Occupational Safety and Health (NIOSH), National Institute of Health (NIH)/ National Institute of Environmental Health Sciences (NIEHS), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), the National Institute of Standards & Technology (NIST), and the Department of Interior's U.S. Geological Survey (USGS). The participating federal agencies have expertise in asbestos-testing and/or asbestos-related issues (e.g., from a health perspective), or because they regulate some of the consumer products that contain talc as an ingredient.

[3] By "consumer products", we are referring to products used by consumers, which are regulated by a variety of federal agencies. This includes, but is not limited to, "consumer products" as defined under the Consumer Product Safety Act.

asbestosis or pleural plaques, or it may lead to the development of lung cancers and mesothelioma. Exposure to asbestos may also lead to the development of other cancers.[4]

Concern about the purity of talc used as a raw material was heightened in the early 1970s when numerous cosmetic products tested positive for asbestos. However, at that time the development of asbestos testing methods was still in its infancy. In 1976, the cosmetics industry implemented voluntary asbestos testing of talc raw materials using the Cosmetic, Toiletry, and Fragrance Association (CTFA) J4-1 method. Talc suppliers to the pharmaceutical industry use a similar method to certify that talc meets the United States Pharmacopeia's (USP's) requirement for "Absence of Asbestos." To date, both methods rely on the use of X-ray diffraction (XRD) or infrared (IR) spectroscopy followed by polarized light microscopy (PLM) only if XRD or IR is positive for amphibole or serpentine minerals in talc. The CTFA J4-1 and USP methods remain standard test methods despite long-recognized shortcomings in specificity and sensitivity compared with electron microscopy-based methods.

In 2010, FDA asked the USP to consider revising the current tests for asbestos in talc to ensure adequate specificity, and in 2014 the Talc USP expert panel recommended an update of the Talc USP monograph to require an electron microscopy method for the measurement of asbestos in talc (Woodcock, 2010[5]; Block et al. 2014[6]). Recent reports from testing of cosmetic products indicate that because of shortcomings in sensitivity, light microscopy (polarized light microscopy; PLM) sometimes fails to detect finely-sized particles of asbestos and similar minerals even when they are present in talc. Moreover, modern laboratories with expertise in asbestos testing, when asked to test talc-containing consumer products, routinely perform electron microscopy and do not rely solely on PLM. These findings provide support to recommendations from many scientific experts, including those on this Working Group, that transmission electron microscopy (TEM) should be used for asbestos-testing of talc, even if the findings of PLM are negative. (See, for example, Rohl and Langer, 1974[7], Millette 2015[8], Block et al. 2014[5]).

There are many definitions of "asbestos" used in the commercial, geological, and legal domains. As a commercial term, asbestos refers to a group of six mined minerals that have commercially useful properties including flexibility, durability, and heat-resistance. Mineralogists define "asbestos" as those silicate minerals belonging to the serpentine and amphibole groups which have an unusual fibrous (asbestiform) crystal growth habit as opposed to non-asbestiform crystal

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[4] *Asbestos: Selected Cancers*, 2006, Institute of Medicine of the National Academy, Committee on Asbestos; International Agency for Research on Cancer (IARC), 2012, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Monograph 100C. A Review of Human Carcinogens: Arsenic, Metals, Fibres, and Dusts.

[5]Woodcock, J. (2010) Letter to Roger L. Williams, CEO of USP (October 12, 2010). See https://www.usp.org/sites/default/files/usp/document/get-involved/monograph-modernization/2010-10-12-letter-from-dr-janet-woodcock.pdf

[6] Block LH, Beckers D, Ferret J, Meeker GP, Miller A, Osterberg RE, Patil DM, Pier JW, Riseman S, Rutstein MS, Tomaino GP, Van Orden DR, Webber JS, Medwid J, Wolfgang S, and Moore K (2014) Stimuli to the Revision Process, Modernization of Asbestos Testing in USP Talc USP-PF 40(4) https://www.fairwarning.org/wp-content/uploads/2017/12/11TalcDoc.pdf

6 Rohl AN and Langer AM. (1974) Identification and quantitation of asbestos in talc. Environ Health Perspect. 9: 95-109.

[8] Millette JR (2015) Procedure for the Analysis of Talc for Asbestos. The Microscope 63(1): 11-20.

growth. US asbestos regulations and the test methods required to establish regulatory compliance specify each regulated type of asbestos using mineral and commercial nomenclature. Most US regulations specify the six asbestos minerals historically used commercially: chrysotile (a member of the serpentine group) and asbestiform riebeckite (commercially called "crocidolite"), asbestiform grunerite-cummingtonite (commercially called "amosite"), tremolite asbestos, anthophyllite asbestos, and actinolite asbestos (with the latter five being members of the amphibole group).

Asbestos regulations and standard methods for analysis contain a wide variety of "counting rules" designating how to quantify asbestos in occupational or environmental settings using various microscopic methods. Rules were tailored to simplify counting, to improve statistical analysis, and to provide a threshold for mitigating risk when asbestos is known to be present. To date, counting rules have not specifically considered biological activity, overt toxicity, or epidemiology of the kinds of chrysotile and amphibole particles being detected and counted. That is, all mineral particles meeting specified criteria for mineral type and dimensions are expected to be reported and counted.

Importantly, testing methods pertaining to asbestos in articles of commerce were developed for analyzing "bulk materials" containing at least 1% asbestos as an intentional ingredient by weight or in settings where asbestos was known to be present (*e.g.* mines, mills, factories, schools, and other settings). Published methods for analysis of bulk materials were not intended to determine the presence of asbestos in products at less than 1% concentration. In contrast, the likely amount present when asbestos is a contaminant or impurity in talc or talc-containing consumer products might be orders of magnitude below 1%.

Because no single published testing method can be followed, as written, for the analysis of asbestos in talc and talc-containing consumer products, analytical laboratories appear to be adapting published testing methods that were intended for analysis of asbestos in air or building materials. Thus, to help reconcile potential discrepancies in reports of analysis, IWGACP recommends the development of a standardized method specifically for the analysis of asbestos and other biologically active EMPs in talc and talc-containing consumer products for use by government regulatory authorities, industry, and contracting laboratories. Rigorous training requirements, quality assurance, and quality control would need to accompany the implementation of these methods to maintain consistency of results across the field.

The difficulty of identifying and quantifying individual asbestos or other mineral particles present at low concentrations in talc is compounded by the presence of non-asbestiform analogs with the same elemental composition and crystal structure, but different growth habit. Using TEM, differentiation of chrysotile from non-asbestiform serpentine analogs is relatively straightforward; however, each of the non-asbestiform amphiboles can disaggregate into particles resembling asbestiform fibers, giving rise to disputes between laboratories over whether elongate amphibole particles are truly asbestos, or are particles resulting from attrition of larger particles of a non-asbestiform analog. Because both types of elongate minerals are suspected of having biological activity with similar pathological outcomes, the distinction is irrelevant. Lack of consensus concerning what should be called "asbestos" has persisted since the first reports indicating that asbestos might be present in talc used in cosmetics and has inhibited thorough toxicological and epidemiological investigations of disease attributable to talc that contains asbestos.

In light of this lack of consensus, the IWGACP considered applicable published asbestos test methods[9] and other published documents in developing recommendations for terminology, analytical techniques, and criteria for qualitative and quantitative measurement of asbestos in talc and talc-containing consumer products. Based on its review, the IWGACP agrees with the recommendations and rationale provided in the peer reviewed NIOSH Bulletin 62[10] regarding adopting the term "elongate mineral particle" or "EMP" that is defined as "*any mineral particle with a minimum aspect ratio* [*i.e.*, length: width ratio] *of 3:1.*" Thus, an EMP encompasses both asbestiform and non-asbestiform particles that have dimensions that enable them to be respirable. NIOSH Bulletin 62 also introduced two terms "covered mineral" and "countable EMP," that appear to be applicable to the analysis of talc and talc-containing products. A "covered mineral" is defined as "*a mineral encompassed by a specified regulation or recommended standard*" and a "countable EMP" as "*a particle that meets specified dimensional criteria and is to be counted according to an established protocol*." However, for talc and talc-containing products, the recommendations for covered minerals and countable EMP dimensions differ from those discussed in Bulletin 62 for the NIOSH recommended exposure limit (REL). For talc and talc-containing products:

- Covered minerals include chrysotile (but not other serpentine minerals) and members of the amphibole group (inclusive; not restricted to the five amphiboles used commercially).
- Countable EMPs have an aspect ratio (AR) of $\geq$3:1 and a length of > 0.5 µm using the most inclusive criteria for length and AR from among the "asbestos" counting rules in established testing protocols. The specified minimum length of 0.5 µm is consistent with the counting rules for fibers established by the global standard for TEM sampling and analysis, ISO 10312:2019 (Appendix C) and is supported by studies that indicate asbestos particles and EMPs of these dimensions could pose a health concern.[11]

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[9] The Cosmetic, Toiletry, and Fragrance Association (CTFA) J4-1 Method (1976): http://www.asbestosandtalc.com/EMP%20Detection%20Limits%20ASTM/PCPC000960.pdf ; United States Pharmacopeia (USP) standard for talc (2011): http://ftp.uspbpep.com/v29240/usp29nf24s0_m80360.html; https://www.astm.org/Standard/standards-and-publications.html; USP Food Chemicals Codex (2019): https://www.foodchemicalscodex.org/ ; various ASTM, ISO, EPA, and NIOSH standards: https://www.astm.org/Standard/standards-and-publications.html; https://www.iso.org/standards.html; https://www.epa.gov/asbestos/asbestos-laws-and-regulations; https://www.cdc.gov/niosh/pubs/all_date_desc_nopubnumbers.html

[10] NIOSH (2011) "Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research" *Current Intelligence Bulletin 62*. Department of Health and Human Services. Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health. Publication No. 2011-159 (March 2011). http://www.cdc.gov/niosh/docs/2011-159/pdfs/2011-159.pdf.

[11] For example, see Suzuki and Yuen (2002) Asbestos fibers contributing to the induction of human malignant mesothelioma. Ann NY Acad Sci 982: 160-176: https://www.ncbi.nlm.nih.gov/pubmed/12562635; Dodson et al. (2003) Asbestos fiber length as related to potential pathogenicity: a critical review. Am J. Ind. Med. 44: 291-297: https://www.ncbi.nlm.nih.gov/pubmed/12929149; Suzuki et al. (2005) Short, thin, asbestos fibers contribute to the development of human malignant mesothelioma: pathological evidence. Int. J. Hyg. Environ. Health 208(3): 201-210: https://www.ncbi.nlm.nih.gov/pubmed/15971859; Boulanger et al. (2014) Quantification of short and long asbestos fibers to assess asbestos exposure: a review of fiber size toxicity. Environmental Health 13:59: https://www.ncbi.nlm.nih.gov/pubmed/25043725; ANSES (2015) Opinion of the French Agency for Food, Environmental and Occupational Health and Safety on "Health effects and the identification of cleavage fragments of amphiboles from quarried minerals": https://www.anses.fr/en/system/files/AIR2014sa0196RaEN.pdf .

The optimal analytical approach should address potential interference by sample matrices and thereby ensure sensitivity at levels or concentrations that are protective of public health. In addition, multiple sampling and analysis methods will be required to provide all the information that is needed to make health protective identification and classification of asbestos and other EMPs of potential concern. To improve agreement in data interpretation among stakeholders and resolve inconsistencies in applying published methods and counting criteria, IWGACP recommends minimum content and format for analytical reports. IWGACP also suggests written protocols that specify appropriate instruments, methods, and counting rules for the detection, quantification, and classification of EMPs. In conclusion, the IWGACP recommends:

1. Adoption of the term EMP as *"any mineral particle with a minimum aspect ratio of 3:1"*, consistent with how this term is defined in the NIOSH Bulletin 62, to resolve ambiguity and disagreement in mineral (asbestos versus non-asbestos) identification.

2. Testing laboratories report all EMPs having length ≥ 0.5 µm (500 nm).

3. That test methods specify reportable EMPs identified as amphibole or chrysotile particles as covered minerals.

4. Test methods require the counting and reporting of covered EMPs as a function of sample mass. When counting, IWGACP recommends referring to guidelines such as ISO 10312 to classify primary and secondary structures. Individual fibers in secondary structures can be counted recording the dimensions of each fiber.

5. Use of TEM at nominally 20,000x magnification, in addition to PLM, to resolve the issues of sensitivity that cause reporting of false negatives for covered EMPs. IWGACP strongly recommends using TEM with energy dispersive X-ray spectroscopy (EDS) and selected area electron diffraction (SAED) analyses to reliably detect and identify chrysotile and asbestiform and non-asbestiform amphibole minerals, including EMPs whose narrowest width is <200 nm (the limit of resolution for light microscopy). SEM might be useful as a complementary method but has significant shortcomings for identification of chrysotile and visualization of the narrowest particles in the population that can only be overcome by using TEM.

6. That "mass percent," a unit that is frequently used to express content of asbestos in commercial bulk materials, is not appropriate for measurement of EMPs in talc and consumer products containing talc because weight percent does not correlate with the number of fibers, and one large fiber could dominate the mass percent value.

7. Although IWGACP concludes that criteria for differential counting and classification of EMPs meeting criteria in #2 would be beneficial, no specific recommendations were agreed upon during deliberations. Therefore, at this time the IWGACP recommends reporting and counting all EMPs of covered minerals under a single classification with additional information that would allow further classification based on measurements such as mineral type and dimensions in the future.

In addition, the IWGACP has identified the following as areas for directing efforts to promote reliability of the analytical methods for asbestos and other EMPs of health concern in talc and talc-containing consumer products:

- Validation of analytical methods (XRD, PLM, TEM) specific to talc and consumer products containing talc that minimize false positive and false negative results.
- Research and validation of methods of sampling that maximize sample representativeness and minimize error and false positives and false negatives.
- Research on methods for sample preparation, in particular, treatments (e.g. "concentration methods") that improve sensitivity while leaving covered minerals unchanged with respect to identity and dimensions.
- Development of talc-specific reference standards with known concentrations of specific EMPs that can be used to assess laboratory and analyst proficiency, increase inter-laboratory concurrence in method validation, minimize reporting errors, and potentially provide for improved reliability of quantitative analysis.

Appendix B

OSHA Report of Evaluation of Cosmetics and Cosmetic Talc for FDA, 23 February 2019.

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U.S. Department of Labor

Occupational Safety and Health
Salt Lake Technical Center
Sandy, Utah 84070

Report of Evaluation of Cosmetics and Cosmetic Talc for FDA
Daniel T Crane
23 February 2019

This report is a response to an Agency Technical Assistance Request dated 23 March 2018 between

The Office of Cosmetics and Colors (OCAC), Center for Food Safety and Applied Nutrition (CFSAN), US Food and Drug Administration (FDA)
and
The Salt Lake Technical Center, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration (OSHA), US Department of Labor

This report presents data and evaluation of the materials examined. It does not express any opinions of OSHA regarding any issues within the purview of the requesting Agency.

Ten different materials were submitted to the Salt Lake Technical Center (SLTC) for evaluation for the presence of asbestos. Eight of the samples were commercial cosmetics. Two samples were talc from different sources. SLTC was instructed to hold one of the samples back without analysis. (Claire's Highlighting Pallet, 945287). Appendix A contains photos and chemistry of each sample. Appendix B documents the samples as received.

The samples were examined by light microscopy, scanning electron microscopy with energy dispersive analysis by X-ray, and X-ray diffraction.

The samples were examined by phase contrast with polarized light illumination (PCM-PLM). The test used is standard at the Salt Lake Technical Center for screening talc samples for amphibole asbestos.[1,2] Samples are mounted in index of refraction liquid n = 1.605 and analyzed using central stop dispersion staining (CSDS). Generally, if any fibers are present which have indices of refraction above 1.605, the samples are analyzed in scanning electron microscopy (SEM) with x-ray energy dispersive analysis (EDX). In this investigation, all samples were analyzed by SEM whether or not fibers were present with indices greater than n = 1.605.

Samples were mounted for examination by SEM and analyzed for the presence of fibers. When a fiber was found, a chemical spectrum was obtained using EDX to determine the chemistry of the mineral. Representative fibers were photo-documented. Initially, the samples were not coated

[1] PCM-PLM analysis procedure given in OSHA Method ID-191 and 29 CFR 1910.1001 Appendix J
[2] Screening test outlined in Dixon, W.C., Applications of Optical Microscopy in Analysis of Asbestos and Quartz, Analytical Techniques in Occupational Health Chemistry, edited by D.D. Dollberg and A.W. Verstuyft. Wash. D.C.: American Chemical Society, (ACS Symposium Series 120) 1980. pp. 13-41.

with a conductive metal (gold) in order that the gold not interfere with the chemical evaluation. The samples were coated with gold and high-resolution photos were obtained. The SEM images in Appendix A are of coated samples, except as noted.

Sub-samples of each submitted sample were examined by wide-angle scan using a Cubix Pro Panalytical X-ray Diffractometer (XRD) and the data evaluated using Rigaku PDXL software for best match and also for forced match to actinolite (card 9001922), anthophyllite (card 9016381), chrysotile (card 1010960), grunerite (card 9000000), riebeckite (card 9004132), and tremolite (card 9003673). In addition to software search, a manual visual search for the presence of the highest three tremolite peaks was performed for each of the submitted samples. None of the XRD results was positive for the presence of any of these regulated asbestos minerals.

Table 1 summarizes the results for the 9 analyzed samples.

Appendix C provides definitions. A fiber is an elongate particle, longer than 5 micrometers and at least three times longer than it is wide. Minerals fitting this criterion are known as elongate mineral particles (EMP).

The second column of Table 1 indicates the presence of elongate mineral particles (EMPs) in the sample. The third column of Table 1 indicates if the EMPs have indices greater than n = 1.605. These have the potential to be amphibole asbestos.

Column 1 is the FDA-assigned number and description of material.
Column 2 indicates whether there are EMPs (possible regulatory fibers) present in the sample
Column 3 indicates whether the EMPs have a morphology consistent with asbestos.
Column 4 indicates the presence of fibers in the SEM.
Column 5 indicates if there are fibers with chemistry consistent with a regulated amphibole.
Column 6 indicates whether or not a regulated mineral was detected by XRD
Column 7 indicates the name of a mineral.

Table 1

Sample Number	Fibers Present in PCM-PLM	Possible amphibole fibers present in PCM-PLM	Fibers Present in SEM	SEM + EDX (chemistry) consistent with regulated minerals	XRD	Regulated asbestos name
761227 Eye shadow	Yes	Yes	Yes	Yes (talc fibers also noted)[1]	ND	Tremolite asbestos
761228 Love	Yes	No	Yes	No (hornblende, other?)[2]	ND	
761230 Compact Powder	Yes	Yes	Yes	Yes (other fiber)[3]	ND	Tremolite asbestos
761231 Contour	Yes	Yes	Yes	Yes	ND	Tremolite asbestos
945288 Shadow & Highlight	Yes	Yes	Yes	No (Ti fiber)[4]	ND	
1027488 Just Shine	Yes	Yes	Yes	Yes (other, hornblende?)[5]	ND	Tremolite asbestos
1036658 NVF talc	Yes	Yes	Yes	No (talc)[6]	ND	
1036659 NVF Talc	Yes	Yes	Yes	Yes (talc)[7]	ND	
5063618 Ombre	Yes	No	Yes	No (Unidentified mineral)[8]	ND	

[1] Both tremolite and talc fibers were found
[2] Amphibole not seen. EMP present that may be a hornblende.
[3] Tremolite was found as well as other unidentified EMP
[4] No amphibole found, titanium oxide fibers found.
[5] Tremolite was found as well as possible EMP that may be hornblende
[6] PCM-PLM showed amphibole, SEM-EDX did not.
[7] Talc fibers found
[8] No amphibole found.

All of the samples had fibers present in PLM.

Samples generally have EMP fibers of multiple minerals.

Samples 761227, 761230, 761231, and 1027488 are positive for elongate particles of tremolite. These fibers appear morphologically fibrous, and likely asbestos. No other species of regulated mineral were found.

All of the results by XRD are ND, none detected. The amount of potential regulated fiber in the samples as noted by PCM/PLM and SEM/EDS is very small and likely below the limit of detection for the XRD, which is generally taken as 1% in practice.

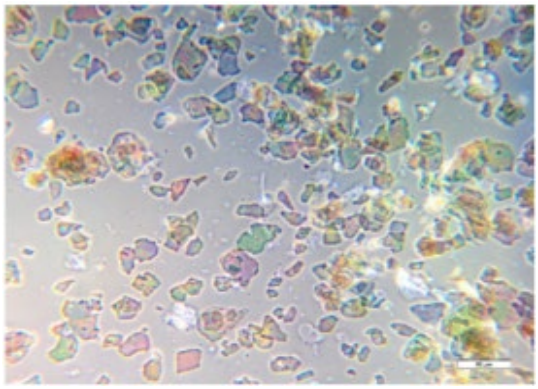
Appendix A contains the photos and chemistry of the samples
Appendix B contains the sample receiving information
Appendix C contains definitions
Appendix D contains preparation and analytical description for PCM and PLM
Appendix E contains preparation and analytical description for SEM and EDS

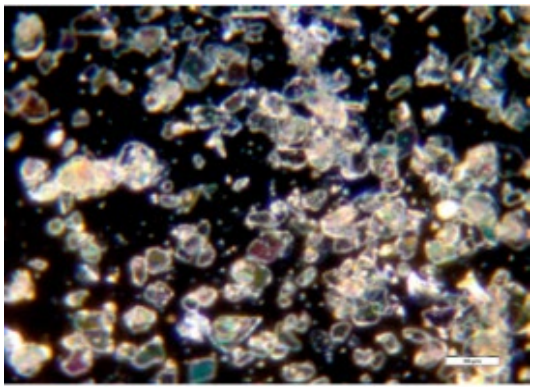
Appendix A

The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

761227

1





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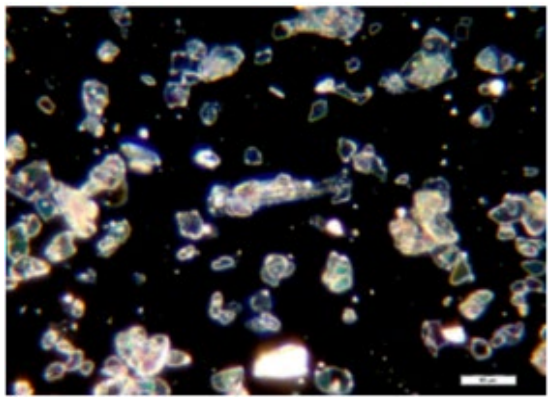

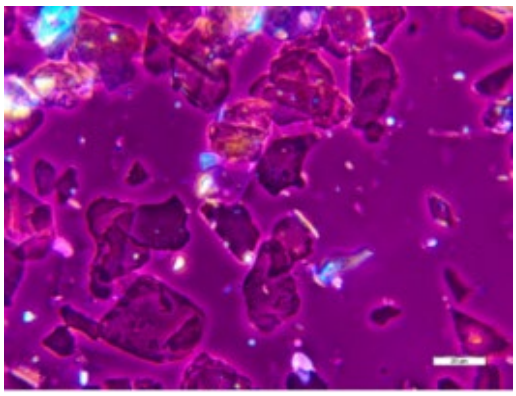

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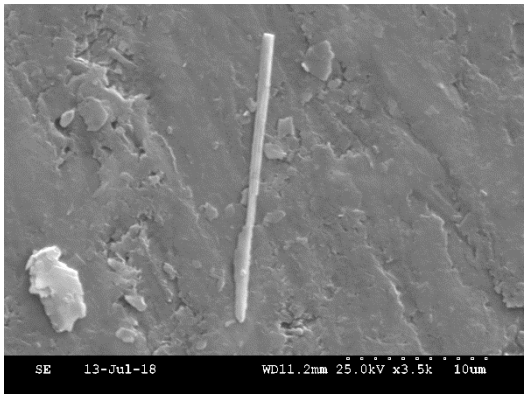
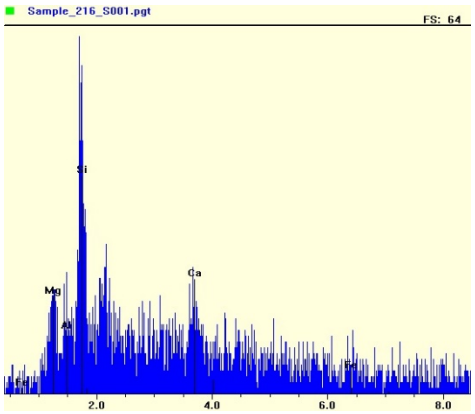




6

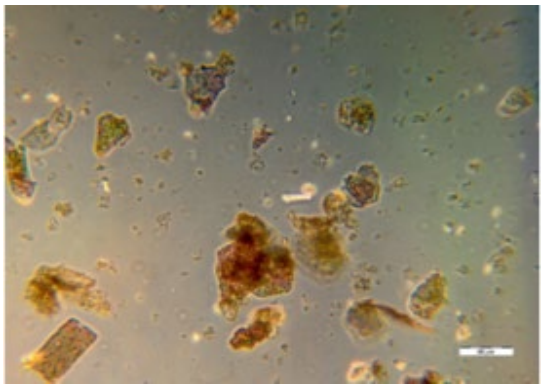
1. Bright Field (PCM) of sample showing a fiber in the center 160X
2. Central Stop Dispersion Stain of the fiber in figure 1. 160X
3. Central Stop Dispersion Stain of a fiber bundle. 160X
4. Crossed polarized light with first order red plate of a fiber in the center 400X
5. SEM of asbestiform tremolite 21 micrometers x 0.7 micrometers
6. EDX spectrum of the fiber in 5, consistent with tremolite.

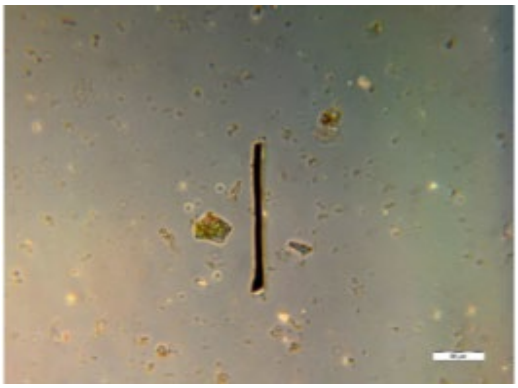
Appendix A

The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

761228

1





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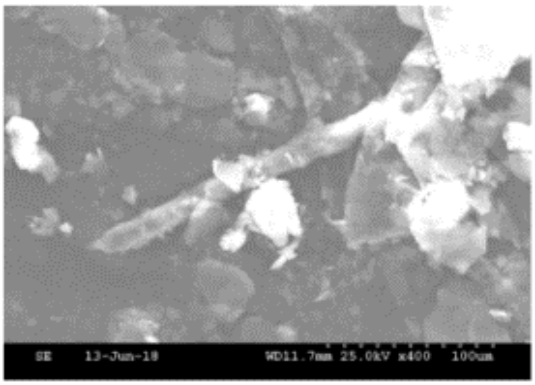

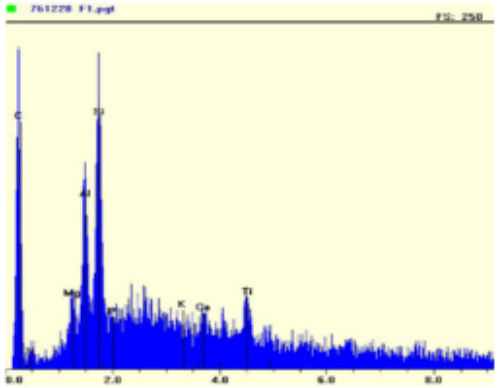

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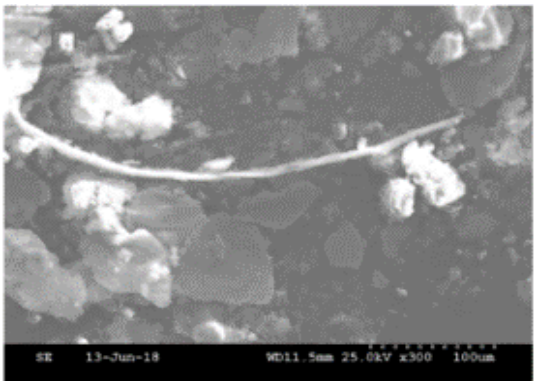
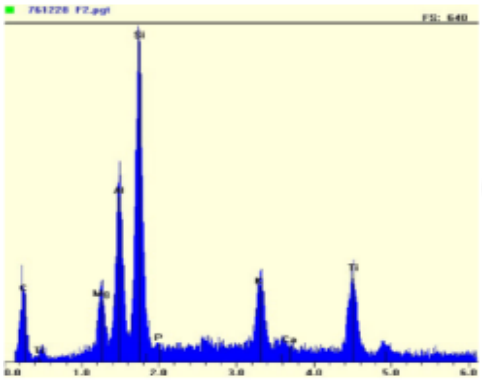




6

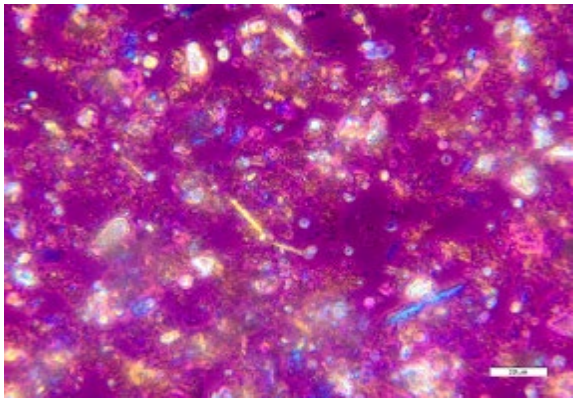
1. Bright Field (PCM) of sample showing a fiber in the center 160X
2. Bright Field (PCM) of sample showing a fiber in the center 160X
3. SEM of non-asbestiform, non-regulated EMP (uncoated with gold)
4. EDX showing Mg, Al, Si, Ti, Ca Not consistent with regulated mineral
5. SEM of non-asbestiform, non-regulated EMP. (uncoated with gold)
6. EDX showing Mg, Al, Si, Ti, Ca Not consistent with regulated mineral. Morphology and chemistry are consistent with organic (plant) fiber.

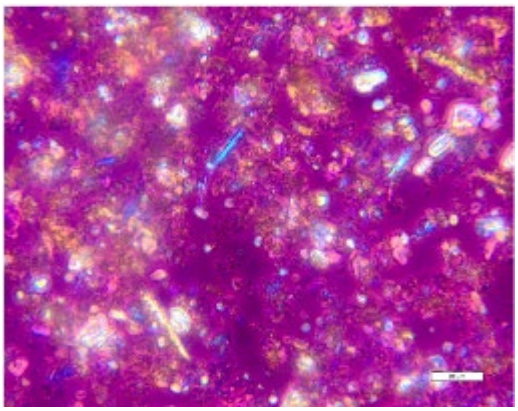
Appendix A

The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

761230

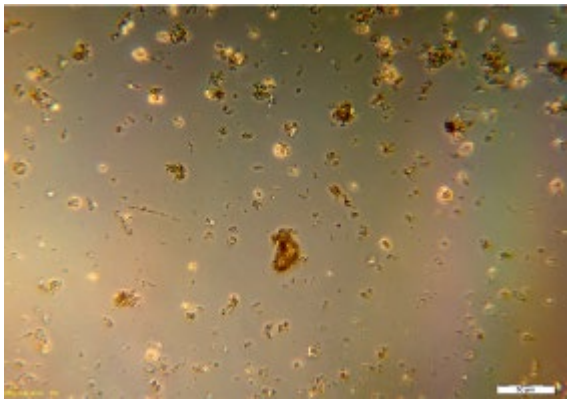
1

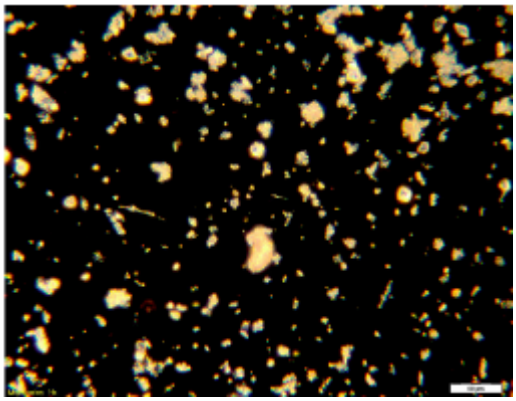




2

3





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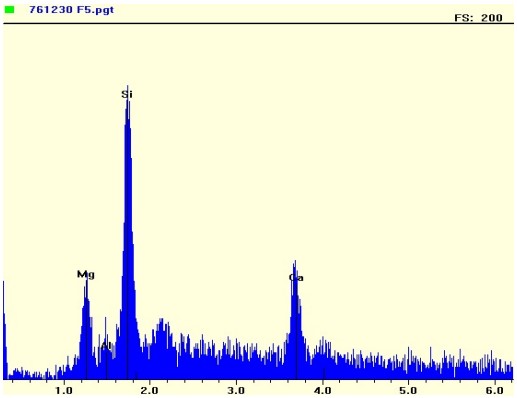


6

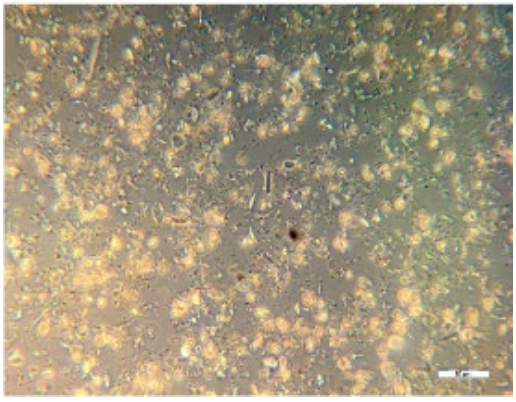
1. PCM-PLM at 400X With several EMPs visible.
2. PCM-PLM with the microscope stage rotated 90º. Note that fibers in photo 1 which appear yellow, appear blue in photo 2 and vice-versa.
3. Bright Field (PCM) 160Xshowing several fibers.
4. Field of Photo 3 in CSDS showing fibers with indices greater than n=1.605 (yellow)
5. SEM photograph of tremolite fiber at 3000X. 23 micrometers x 0.7 micrometers.
6. EDX spectrum of top fiber in Photo 5. It is consistent with tremolite.

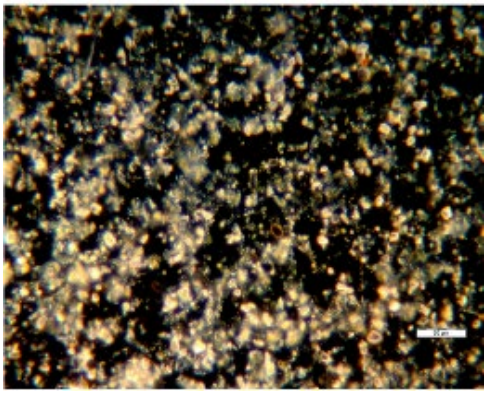
Appendix A

The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

761231

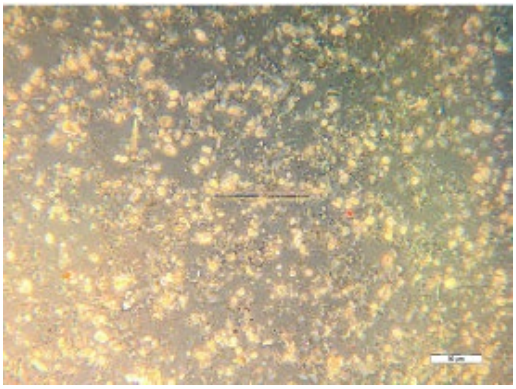
1

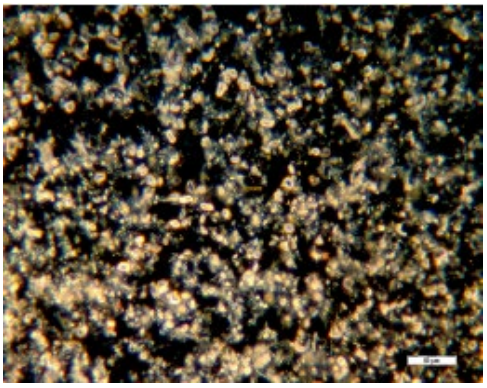




2

3





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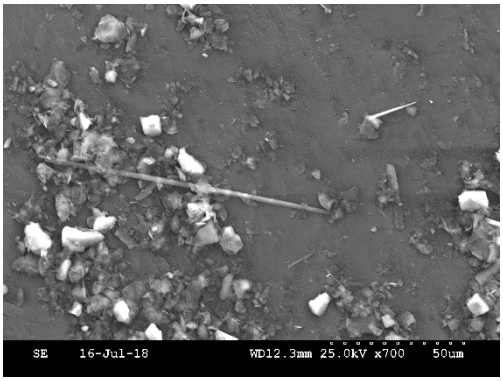
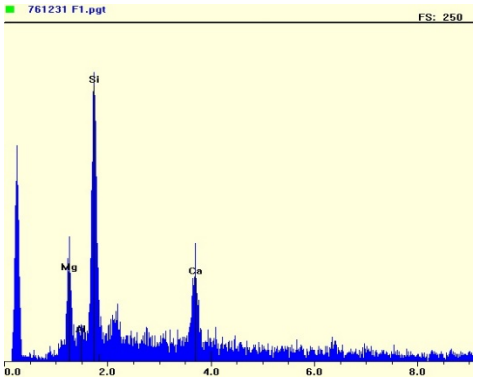
5





6

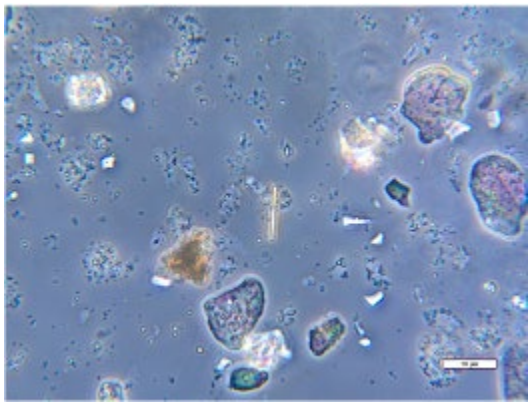
1. Bright Field (PCM) 160Xshowing several fibers
2. Field of Photo 1 in CSDS showing fibers with indices greater than n=1.605 (yellow)
3. Bright Field (PCM) 160Xshowing a long fiber.
4. Field of Photo 3 in CSDS showing fibers with indices greater than n=1.605 (yellow)
5. SEM of asbestiform tremolite. 700X. 109 micrometers x 0.4 micrometers.
6. EDX spectrum of the fiber in 5, consistent with tremolite.

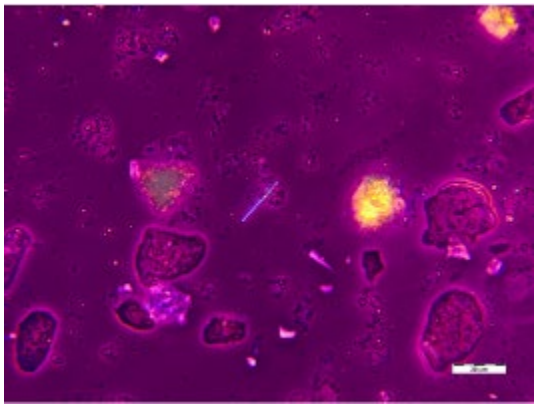
Appendix A

The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

945288

1





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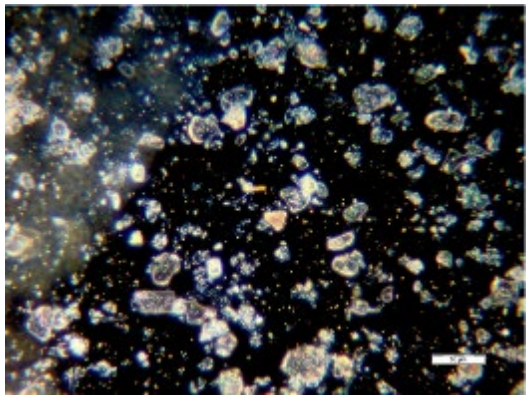
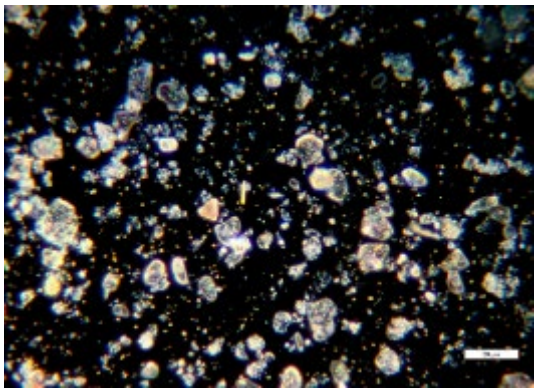
3





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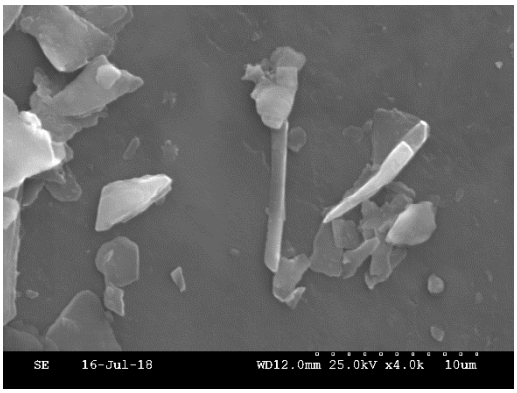
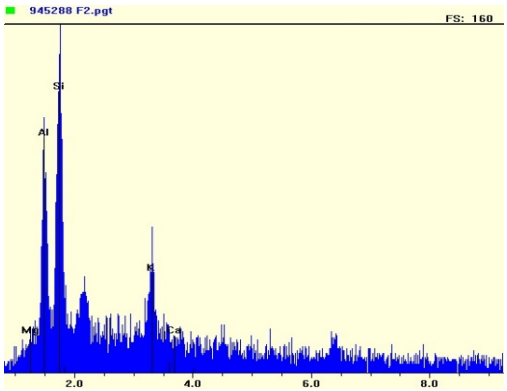




6

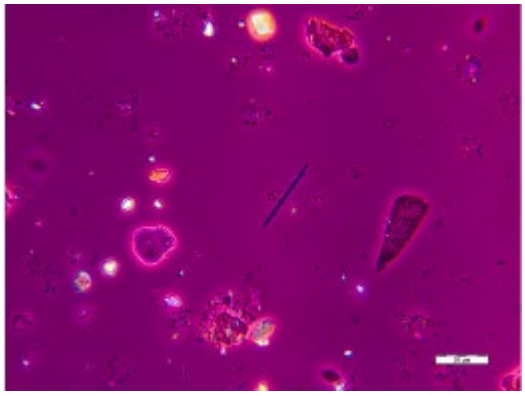
1. Bright Field (PCM) 160Xshowing several fibers 400X
2. PCM-PLM of fiber in Photo 1 160X
3. CSDS of fiber in Photo 1 showing index greater than n=1.605
4. CSDS of fiber rotated 90º to Photo 1 showing index greater than n=1.605
5. SEM of typical fiber
6. EDX of the long fiber in Photo 5 showing K with Al and Si. Not a regulated mineral.

Appendix A

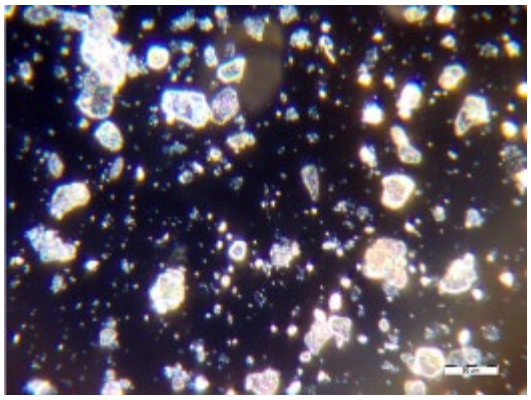
The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

1027488

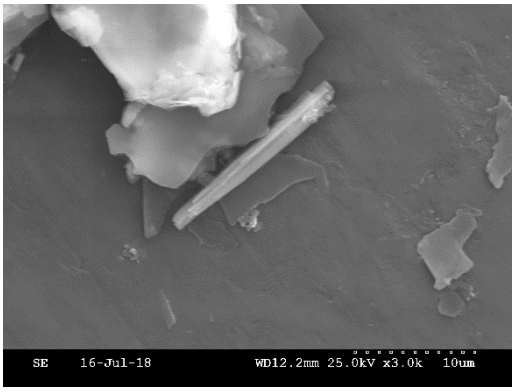
1



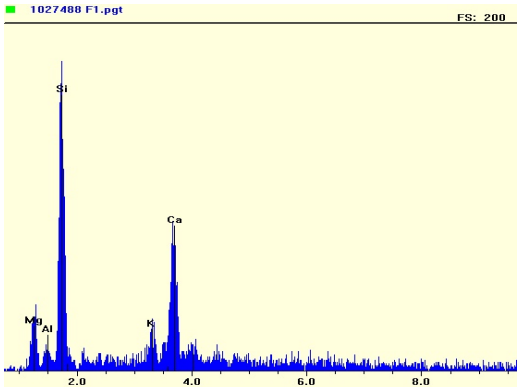
2



3

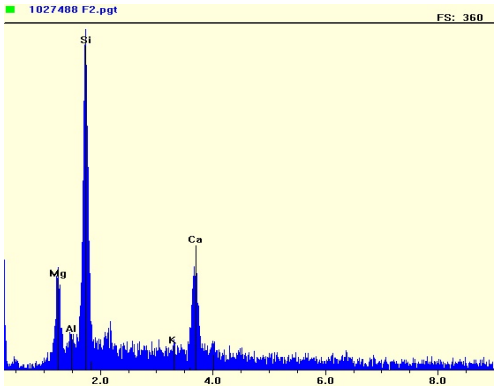


4



5

6



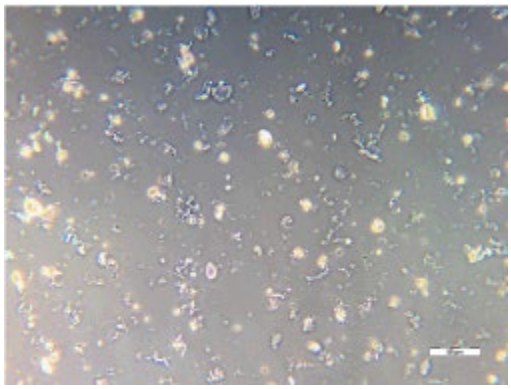
1. PCM-PLM of EMP at 400X
2. CSDS of fiber in Photo 1 showing index of refraction greater than n=1.605
3. SEM of tremolite fiber3000X 17.3 micrometers x 1.8 micrometers.
4. EDX of the tremolite fiber in Photo 3
5. SEM of tremolite fiber 5000 X 14.5 micrometers x 0.9 micrometers.
6. EDX spectra of the fiber in 5.

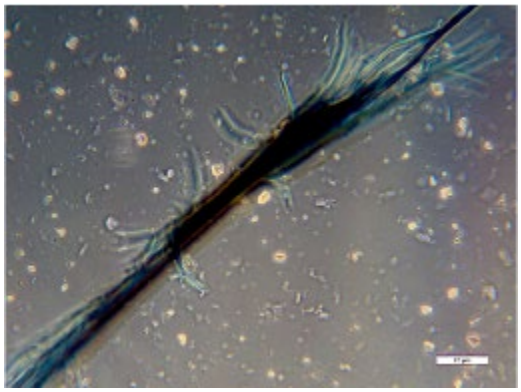
Appendix A

The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

1036658

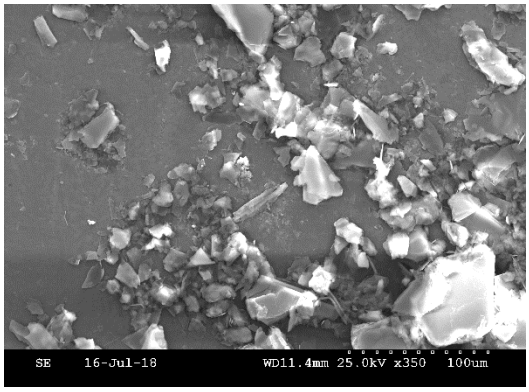
1

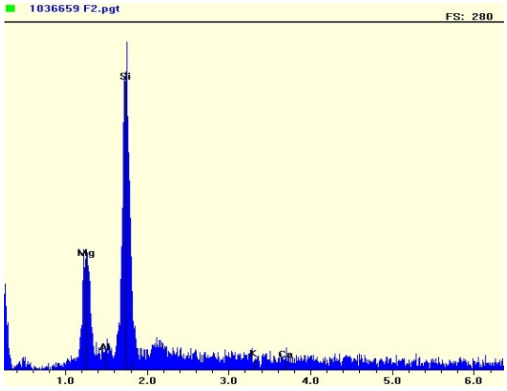




2

3





4

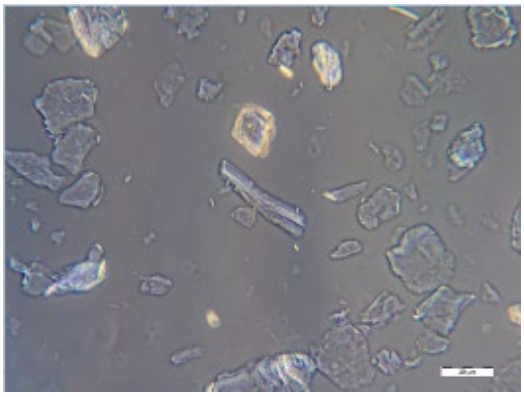
1. Bright Field PCM at 160X
2. Bright Field PCM at 160X organic (plant) fiber
3. SEM Elongate particle
4. EDX of particle in Photo 3. The particle is talc.

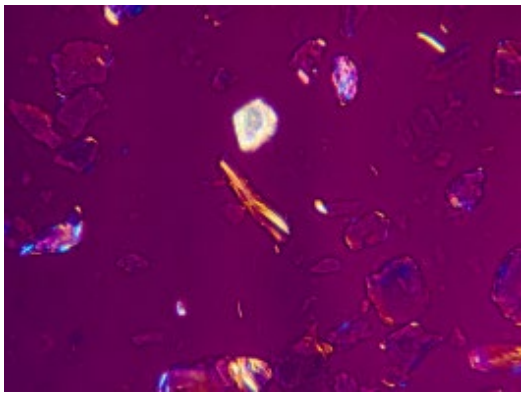
Appendix A

The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

1036659

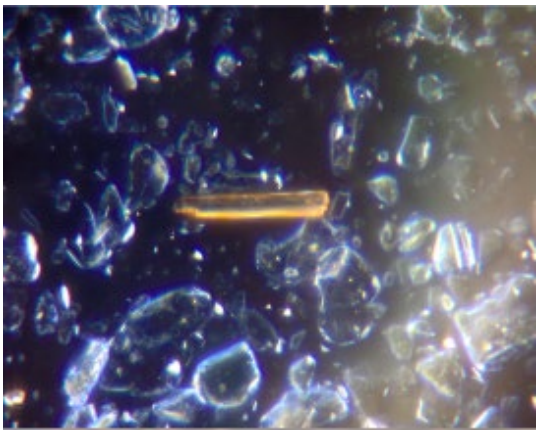
1

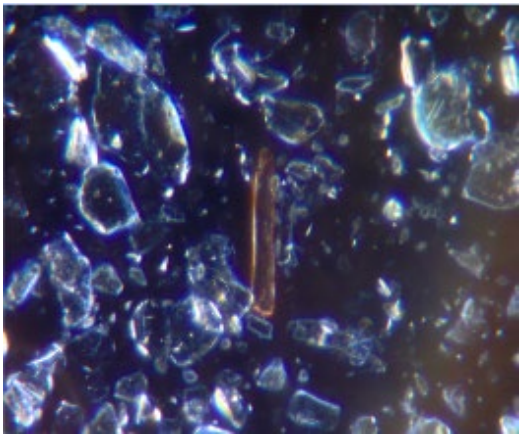




2

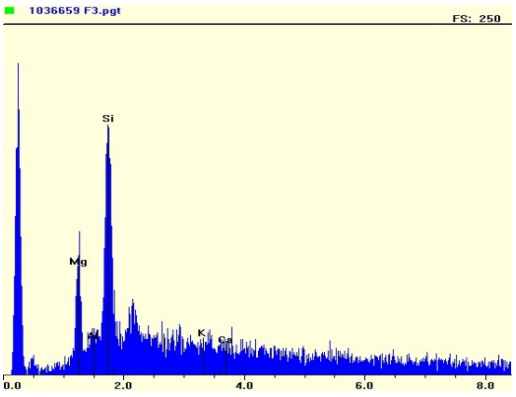
3





4

5



6

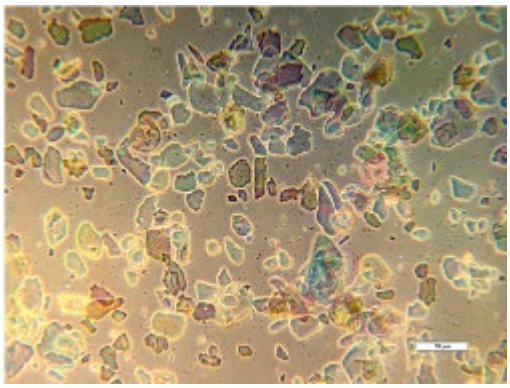
1. Bright Field PCM 400X asbestiform
2. PCM-PLM 400X same fiber as photo 1
3. CSDS of fiber 160X index greater than n=1.605
4. CSDS of fiber 160X index greater than n=1/605
5. SEM of EMP
6. EDX of fiber in Photo 5. The particle is talc.

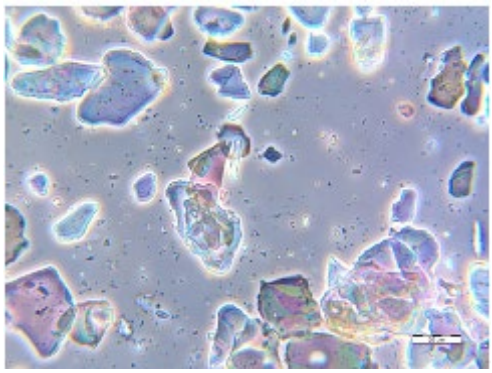
Appendix A

The following are photos and spectra of the samples. Not every type of photo is provided for every sample. Scale bars are included in the light microscopy samples.

5063618

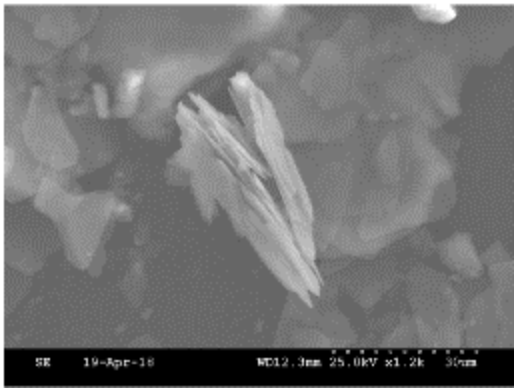
1

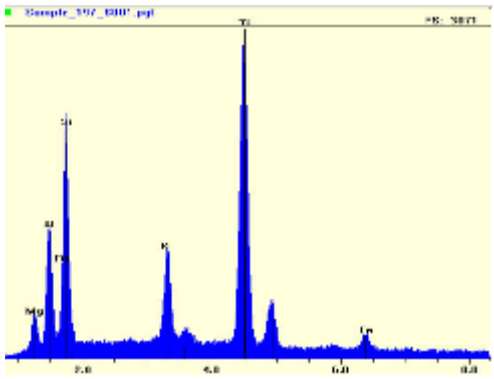




2

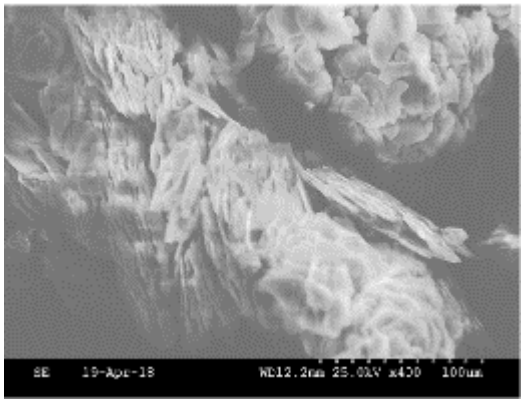
3

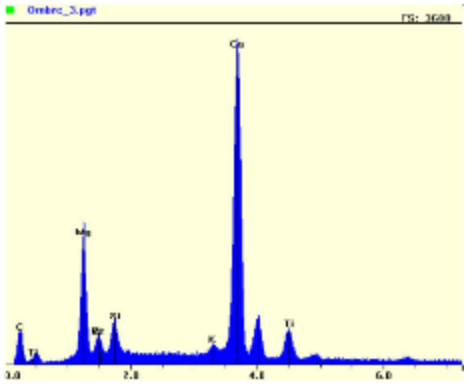




4

5





6

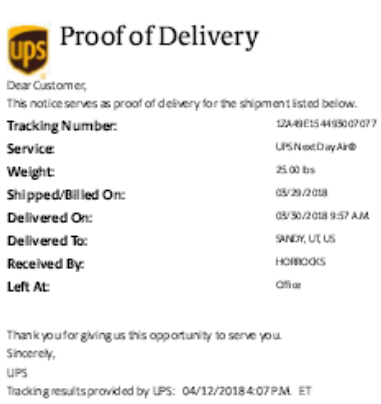
1. Bright Field PCM 160X some EMP
2. Bright Field PCM 400X some EMP
3. SEM EMP, foliar morphology, (uncoated with gold)
4. EDX of particle in Photo 3. NOT regulated mineral
5. SEM EMP, foliar morphology, (uncoated with gold)
6. EDX of particle in Photo 5. NOT regulated mineral

Appendix B -- Receipt of Samples

Firm Name	Product Description	Shipping Information and Sample Identification
Claire's 761227	Eye shadow pallet SKU84716	UPS 1ZA49E154493007077 INV 761227 (rcd. 30 March 2018) (14 boxes)
Claire's 761228	Love labeled box of mixed product SKU33411	UPS 1ZA49E154492098463 INV 761228 (rcd. 30 March 2018) (12 boxes with 2 units each)
Claire's 761230	Compact Powder	UPS 1Z A49E150196670130 761230 (rcd 10 May 2018) (24 units)
Claire's 761231	Contour	UPS 1ZA49E150196670130 761231 (RCD 10 May 2018) (24 units)
Claire's 945288	Shadow & Highlight	UPS 1ZA49E150196670130 945288 (RCD 10 May 2018) (27 units)
Tween Brands 1027488	JUSTICE JUST SHINE SHIMMER POWDER	UPS 1Z2R3A560107281092 1027488 (rcd. 30 March 2018) (6 units)
Beauty Plus 5063618	CITY COLORS SHIMMER OMBRE HIGHLIGHT PINK OPAL C-0025A (SK-17061A)	UPS 1Z2R3A560107281092 1030370 (rcd. 20 March 2018) (6 boxes with 2 units each)
1036658 NVF talc	FDA sample and sampling equipment	UPS 1ZA4744W8591420444 (rcd 27 March 2018) 2 bottles and assorted implements
1036659 NVF talc	FDA sample and sampling equipment	UPS 1ZA4744W8591420444 (rcd 27 March 2018) 2 bottles and assorted implements
Claire's 945287 **NOT ANALYZED PER FDA REQUEST**	Highlight Highlighting Palette UPC 61960-1	UPS 1ZA49E154494870454 INV 945287 (rcd. 30 March 2018) (26 boxes with 2 units each)

Appendix B -- Receipt of Samples

Sample INV 761227 was received in a single box Salt Lake Technical Center on 30 March 2018. Sample INV 761227 consisted of 14 boxes (units).



Proof of Delivery

Dear Customer,

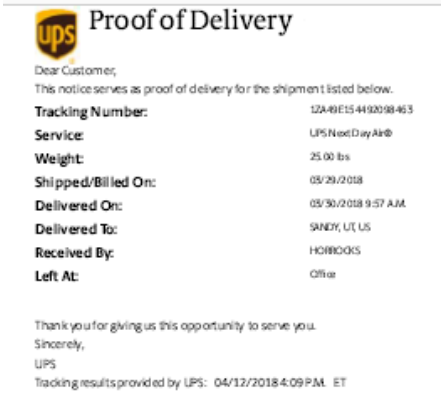
This notice serves as proof of delivery for the shipment listed below.

Tracking Number:	1ZA48E154490307077
Service:	UPS Next Day Air®
Weight:	25.00 lbs
Shipped/Billed On:	03/29/2018
Delivered On:	03/30/2018 9:57 A.M.
Delivered To:	SANDY, UT, US
Received By:	HORROCKS
Left At:	Office

Thank you for giving us this opportunity to serve you.
Sincerely,
UPS
Tracking results provided by UPS: 04/12/2018 4:07 P.M. ET

Appendix B -- Receipt of Samples

Sample 761228 was received in a single box Salt Lake Technical Center on 30 March 2018. Sample 761228 consisted of 12 boxes with 2 units each.



Proof of Delivery

Dear Customer,

This notice serves as proof of delivery for the shipment listed below.

Tracking Number:	1ZA49E154492098463
Service:	UPS Next Day Air®
Weight:	25.00 lbs
Shipped/Billed On:	03/29/2018
Delivered On:	03/30/2018 9:57 A.M.
Delivered To:	SANDY, UT, US
Received By:	HORROCKS
Left At:	Office

Thank you for giving us this opportunity to serve you.
Sincerely,
UPS
Tracking results provided by UPS: 04/12/2018 4:09 P.M. ET

Appendix B -- Receipt of Samples

Proof of Delivery

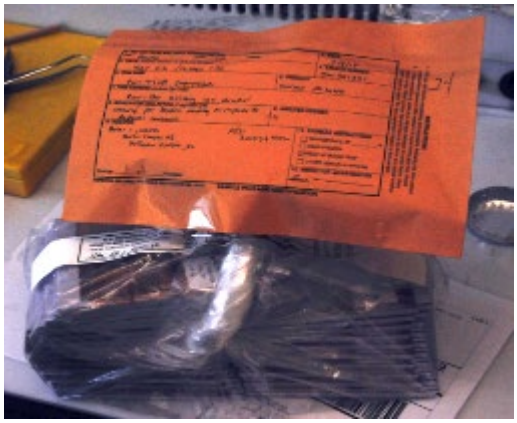
Dear Customer,

This notice serves as proof of delivery for the shipment listed below.

Tracking Number:	1ZA49E150196670130
Service:	UPS Next Day Air®
Weight:	25.00 lbs
Shipped/Billed On:	05/09/2018
Delivered On:	05/10/2018 9:57 A.M.
Delivered To:	SANDY, US
Received By:	HORROCKS
Left At:	Office

Sample 761230, 761231 and 945288 were received in a single box Salt Lake Technical Center 5on 30 March 2018. Sample 761230 consisted of 24 units, sample 761231 consisted of 24 units and sample 9455288 consisted of 27 units.

761230



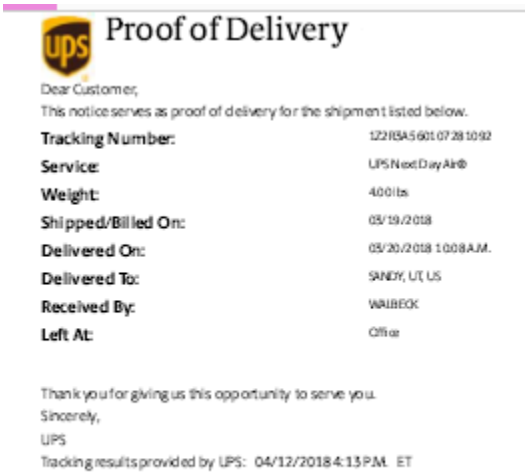
761231

Appendix B -- Receipt of Samples

945288

Appendix B -- Receipt of Samples

Samples 1027488 and 1030370 were received in a single box at the Salt Lake Technical Center on 20 March 2018. Sample 1027488 consisted of 6 units. Sample 1030370 consisted of 6 boxes with 2 units each



Proof of Delivery

Dear Customer,

This notice serves as proof of delivery for the shipment listed below.

Tracking Number:	1Z2R8A560107281092
Service:	UPS Next Day Air®
Weight:	4.00 lbs
Shipped/Billed On:	03/19/2018
Delivered On:	03/20/2018 10:08 A.M.
Delivered To:	SANDY, UT, US
Received By:	WALBECK
Left At:	Office

Thank you for giving us this opportunity to serve you.
Sincerely,
UPS
Tracking results provided by UPS: 04/12/2018 4:13 P.M. ET

Appendix B -- Receipt of Samples

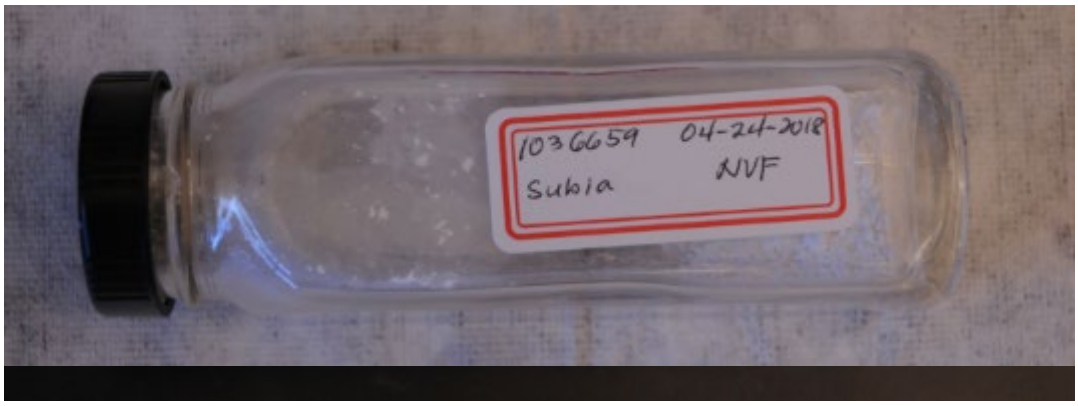
Samples 1036658 and 1036659 were received in a single box. Each consisted of two glass bottles of white powder and a bag containing sampling implements. The sampling implements were set aside and have not been analyzed.

Proof of Delivery

Dear Customer,

This notice serves as proof of delivery for the shipment listed below.

Tracking Number:	1ZA4744W8591420444
Weight:	7.00 lbs
Shipped/Billed On:	04/25/2018
Delivered On:	04/27/2018 9:41 A.M.
Delivered To:	SANDY, US
Received By:	HORROCKS
Left At:	Office



Note: Sampling implements not shown.

Appendix B -- Receipt of Samples

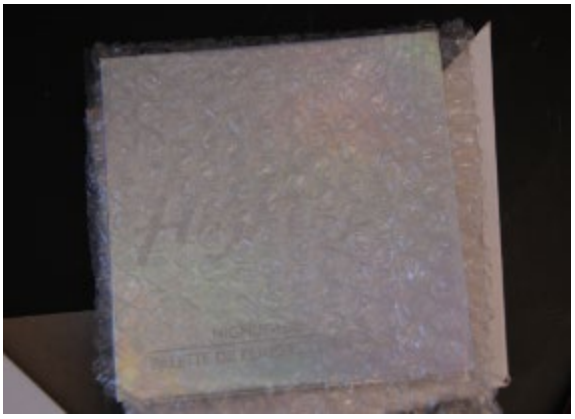
Sample INV 945287 was received in a single box Salt Lake Technical Center on 30 March 2018. Sample INV 945287 consisted of 26 boxes with 2 units each.

Proof of Delivery

Dear Customer,
This notice serves as proof of delivery for the shipment listed below.

Tracking Number:	1ZA481E54494870454
Service:	UPS Next Day Air®
Weight:	25.00 lbs
Shipped/Billed On:	03/29/2018
Delivered On:	03/30/2018 9:57 A.M.
Delivered To:	SANDY, UT, US
Received By:	HORROCKS
Left At:	Office

Thank you for giving us this opportunity to serve you.
Sincerely,
UPS
Tracking results provided by UPS: 04/12/2018 4:02 P.M. ET



Appendix C -- Definitions for Regulated Asbestos

In order to avoid any confusion, the following nomenclature is used. This is based upon the definitions that have been established by regulation and litigation.[3, 4]

Asbestos includes only the minerals chrysotile, Amosite, crocidolite, tremolite asbestos, anthophyllite asbestos, and actinolite asbestos.[5] An asbestos mineral has a fibrous growth habit.

Asbestiform The term "asbestiform" is not a growth habit. It is a description of a mineral which has a fibrous growth habit. The growth habit used in mineralogy is "fiber." Individual fibers of asbestos are held together by Van der Waals forces rather than ionic or covalent bonds.

> "It (asbestiform) is an inherent, fine-textured morphology in a mineral. Resulting from unequal relative development of the principle crystal faces, which ideally produces a predominant release of strong, flexible fibers having (1) microscopic to submicroscopic diameter and (2) and aspect ratio often exceeding 20:1, when the mineral is subjected to comminution."[6]

Fibrous is a mineralogical term for growth habit for crystals that are composed of long thin fibers. In mineralogy, there is no fixed aspect ratio (length to width ratio) that defines a fiber. Commonly used aspect ratios are 3:1, 5:1, 10:1, 20:1 and 100:1 depending upon use. In regulation, a 3:1 aspect ratio is established by regulation and case law.

A **regulatory fiber** is a fiber of asbestos

1. Having an aspect ratio greater than or equal to 3:1
2. Longer than or equal to 5 micrometers
3. Visible in a phase contrast microscope (PCM)

A **fibril** is a single crystal of an asbestiform mineral. A fibril, is, by definition, a fiber. Fibrils nominally have diameters of about 50 nm for chrysotile and about 100 nm for amphiboles (depending upon the species and growth conditions.).

A **bundle** is an assembly of fibrils and is usually considered to be a fiber.

A **matrix** is a matted mass of fibers, considered a regulatory fiber if one or more fibers extends 5 micrometers from the mass. (In the TEM, a matrix is considered equivalent to one fiber)

Elongate particle (EMP) is a particle with an aspect ratio generally longer than 3:1 regardless of whether it is fibrous or is elongate due to comminution (grinding).

Growth habit Crystal habit is the tendency for specimens of a mineral to repeatedly grow into characteristic shapes.[7]

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[3] Secretary of Labor v Borg Warner, OSHRC Docket No. 10757, 22 February 1978
[4] 29 CFR 1910.1001 and others, Occupational Safety and Health Administration,
[5] 29 CFR 1910.1001 (b) definitions
[6] Definitions for Asbestos and other Health-related silicates, Levadie, B., ASTM STP834, 1982
[7] https://geology.com/minerals/crystal-habit/

Appendix D
PCM-PLM-Dispersion Staining Go/No-Go Test for Amphibole Fibers in Talc

The PCM-PLM Dispersion Staining Go/No-Go test is used as a screening test to determine whether or not amphibole fibers are present in powdered samples of talc.

A sample is examined using a polarizing phase-contrast microscope (PCM-PLM) at 400X and 160X magnifications. Any fibers meeting the federal definition for asbestos will be visible because of the use of PCM. Fibers with diameters greater than 0.5 to 1 micrometer may be examined for the presence of retardation colors. If there are any visible fibers, they are examined using central stop dispersion staining (CSDS) using the same microscope.

A preparation of powdered sample is made in high-dispersion refractive index liquid with n = 1.605. The observable indices of refraction of all of the regulated amphiboles are greater than 1.605, while the indices of refraction for talc is less than n = 1.605.

Because of this, the central-stop dispersion staining (CSDS) colors observed for amphiboles will indicate that the particle indices are greater than the index of the liquid. Generally, this will be yellow orange to yellow, or yellow-white. Talc, brucite and chrysotile fibers will be blue to blue-white.

If there are no fibers with CSDS colors indicative of possible amphibole present (e.g. yellow to yellow white) then it is unlikely that any amphibole asbestos is present.

When fibers are visible that have CSDS colors indicating indices greater than n = 1.605, further examination in matching liquids as well as other measurements are required to identify the amphibole.

The index of refraction liquid n = 1.605 is not a matching liquid for talc or any amphibole and is insufficient to identify any of the regulated minerals.

The samples submitted for this investigation were either packed powder or loose powder. All were apparently dry with no apparent wetness, equilibrated to the local humidity.

For this examination, no gravimetric reduction was performed. (e.g. the samples were not subjected to acid, heat or chemicals designed to remove unwanted substances, and examined as received.).

Samples were prepared individually in a table-top laboratory hood, and all instruments and horizontal surfaces were cleaned in between samples. This is a measure to prevent cross-contamination between the samples.

At least three separate slide preparations were made and examined for each of the samples.

1. Two to three drops of high dispersion index of refraction liquid are allowed to drop by gravity onto the surface of a cleaned 1 x 3 in. glass slide.
2. A clean dissecting needle is used as a sampling probe. The tip is wetted in the index of refraction liquid on the slide and then dipped into the sample. A small amount of powder

clings to the dissection needle. The amount is determined by the diameter of the captured powder clump and is usually less than a 0.5 mm.

3. The dissection needle with the powder is introduced into the liquid on the slide and stirred gently to disperse the powder as evenly as possible.
4. A clean, No 1 ½ glass cover slip is gently lowered onto the liquid.

NOTE 1: The amount of index of refraction liquid placed on the slide in step 1 is determined by experience such that little to no liquid extends beyond the boundary of the cover slip.

NOTE 2: If the preparation is cloudy, it indicates that too much powder was on the dissection needle when the powder was sampled. Discard this preparation and perform steps 1 to 4 using a smaller amount of powder until a suitable preparation is made. Too much powder in the preparation will interfere with the optical tests. These tests generally depend on particles being dispersed in the liquid sufficiently far apart so that their images do not interfere with one another.

Examination

A phase contrast microscope which also has crossed polarizing elements and a first-order red compensator is used to examine the samples. (See OSHA ID-191 for a full description of PCM-PLM examination.)

A slide preparation is placed on the microscope stage and examined at 160X and 400X. (The sample may also be examined at 100X if the microscope is equipped for PCM at 100X. In this particular investigation, little use was made of the 100X magnification because the particles were very finely divided.)

An initial scan of the slide is made at 160X and 400X to note the presence of any elongate particles. The morphology of any observed elongate particle is evaluated whether it is, organic, synthetic or mineral, and if mineral, consistent with asbestiform growth habit or other growth habit. Any observed fiber is evaluated for the presence of birefringence observed as retardation colors.

Any mineral fibers are examined at 160X using CSDS. If the colors observed indicate that the fiber may be amphibole, further analysis of the sample is indicated. The sample prep is scanned at 160X to determine if any amphibole source mineral is present.

Appendix E

Preparation and Analysis of Samples by Scanning Electron Microscopy and X-ray Energy Dispersion

The samples were examined by scanning electron microscopy (SEM) and x-ray energy dispersive analysis (EDX). In combination, SEM and EDX provide visual evidence of the morphology of the fibers and a semi-quantitative measure of which elements are present in individual particles.

The SEM uses a beam of electrons accelerated to a high voltage focused to a point and scanned across the surface of the sample. Secondary electrons generated when the beam strikes the sample are used to form a dimensional image of the surface of the sample. At each point where the primary electron beam strikes the sample, x-rays are generated which have energies characteristic of the elements at that location. These x-rays are captured, and the energies analyzed to provide a spectrum representing the elements present in the particle.

Samples for SEM are made by applying a very small amount of powder on a spectrometrically pure carbon adhesive surface on a carbon SEM mount. The powder is smeared onto the surface in a very sparse layer to provide adequate separation between the particles. If the particles are too close, the analytical signal may be affected by other particles nearby.

For high resolution images, conductive coatings are evaporated or sputtered onto SEM samples to render the surface sufficiently conductive electrically that the surface cannot build up a surface charge and degrade the image.

In the first analytical trial, the samples were examined in the SEM without any conductive coating. This was to obtain particle spectra free of any interference from the conductive metal. However, images obtained without a metal coating do not have the resolution necessary to reveal the fine structure of the surfaces of non-conductive particles. During the analysis, it was noted that there were no elements intrinsic to the particulate present in the cosmetics that preclude the use of gold as a coating metal.

A second analytical trial looked at selected samples which have been coated with sputtered gold to a thickness of 5 to 10 Å (0.5 to 1 nm). This thickness is less than the analytical resolution of the SEM, but sufficient to provide a conductive surface and thereby a better evaluation of the morphology of the fibers.

The SEM used for this is a Hitachi S-3500 VP. It was operated in high vacuum mode at and acceleration voltage of 25kV and a working distance of 10mm. A variety of magnifications were used as noted on the photographs. Magnifications greater than about 2,000X were not usable for uncoated samples. Gold coating is necessary for higher magnification evaluation.

The surface of the samples were scanned at between 500 and 1000X to find any fibers. When found, the electron beam is focused on a single spot on the fiber and an EDX spectrum is collected and a determination as to the possible identification of the mineral. Fibers are photo-documented as well as a corresponding EDX spectrum.